Percutaneous transluminal coronary rotational atherectomy for lesions of the coronary arteries

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The Medical Services Advisory Committee is an independent committee which has been established to provide advice to the Commonwealth Minister for Health and Ageing on the strength of evidence available on new medical technologies and procedures in terms of their safety, effectiveness and cost-effectiveness. This advice will help to inform Government decisions about which new medical services should attract funding under Medicare.

This report was prepared by the Medical Services Advisory Committee with the assistance of Dr Elmer V Villanueva, Ms Emily S Petherick and Dr Paul A Fennessy from the Centre for Clinical Effectiveness, Monash Institute of Health Services Research, at Monash University. The report was endorsed by the Commonwealth Minister for Health and Ageing on 17 September 2002.

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MSAC recommendations do not necessarily reflect the views of all individuals who participated in the MSAC evaluation.

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Percutaneous transluminal coronary rotational atherectomy (PTCRA) is one of the newer cardiac interventional devices used to treat coronary artery stenoses. Rather than increasing luminal diameter by arterial stretching and plaque fracture as with percutaneous transluminal coronary angioplasty (PTCA), PTCRA uses an abrasive, diamond-coated burr to debulk existing plaque and calcified lesions by reducing them to small particles (approximately 5μm). When inserted into the appropriate coronary artery with the legion, the rotating burr selectively removes hard tissue, soft tissue being deflected by the elastic recoil of normal segments of vessel.

Medicare Services Advisory Committee – role and approach

The Medical Services Advisory Committee (MSAC) is a key element of a measure taken by the Commonwealth Government to strengthen the role of evidence in health financing decisions in Australia. MSAC advises the Commonwealth Minister for Health and Ageing on the evidence relating to the safety, effectiveness and cost-effectiveness of new medical technologies and procedures, and under what circumstances public funding should be supported.

A rigorous assessment of the available evidence is thus the basis of decision making when funding is sought under Medicare. A team from the Monash Institute of Health Services Research at Monash University was engaged to conduct a systematic review of the literature on percutaneous transluminal coronary rotational atherectomy. A supporting committee with expertise in this area then evaluated the evidence and provided advice to MSAC.

MSAC's assessment of percutaneous transluminal coronary rotational atherectomy

Clinical need

Cardiovascular disease is responsible for 41 per cent of all deaths in Australia. Minimally invasive interventional techniques, such as PTCA, and coronary artery bypass graft (CABG) surgery are the therapeutic modalities most often performed in patients with identified coronary artery disease. While the number of CABG procedures appears to be levelling out, PTCA procedures are still rising. However, both the absolute number and proportion of PTCRA procedures performed annually are variable, with numbers decreasing in the two most recent years during which data were collected. Overall, it is estimated that around two per cent of patients undergoing PTCA will benefit from PTCRA. In 2001, this figure is estimated to be between 370 and 472, depending on the assumptions used to extrapolate from available data. While PTCRA is most often used as an adjunctive procedure to PTCA, it can also be used to treat those who might not cope well with CABG surgery.

Safety

The available evidence from RCTs suggests that PTCRA with or without PTCA is no more likely to result in death, Q-wave infarcts or emergency surgery compared to PTCA alone either during the in-hospital period or within six months of the procedure. Patients are also less likely to experience angiographic dissection or proceed to bailout stenting. However, as this review went to print, vom Dahle *et al.* 2002 published six month data from the ARTIST RCT (in which in-stent restenosis was assessed following PTCRA and PTCA) reporting that six month event-free survival was significantly higher after PTCA (91.3 per cent) compared with PTCRA (79.6 per cent, p=0.0052). PTCRA of in-stent restenosis may have a poorer safety outcome than PTCA.

Since perforation rates (the major and most immediately recognisable adverse event associated with interventional cardiology procedures) are not statistically significantly different from those associated with PTCA, it would appear the PTCRA is as safe as PTCA in the first 24 hours of the procedure. However, minor complications such as temporary vessel spasm and slow flow are more likely. To date, there is insufficient data to conclude whether PTCRA is as safe as PTCA in revascularising different types of coronary artery lesions.

Effectiveness

When conventional PTCA, with or without stent placement, is feasible (95 per cent of cases), PTCRA appears to confer no additional benefit to the patient. This conclusion is supported by evidence from randomised trials.

In cases of in-stent restenosis, there is limited and conflicting published evidence, and no long-term data, to support the routine use of rotational atherectomy. Expert clinical opinion indicates that, in certain circumstances, rotational atherectomy is a useful adjunctive procedure to increase the success of subsequent angioplasty in achieving satisfactory revascularisation in complicated or calcified lesions.

In specific cases where conventional angioplasty and stenting cannot be undertaken successfully or is associated with a poor clinical or angiographic outcome, PTCRA appears to be an effective adjunctive procedure to increase the likelihood of successful revascularisation. This conclusion is supported by evidence from case series and clinical experience; however, it may not be possible to undertake randomised trials to verify this.

Cost effectiveness

Cost-effectiveness ratios could not be determined given the limitations of the data on effectiveness and the paucity of robust cost estimates arising from high-quality studies. Australian cost data demonstrate that PTCRA, used as an adjunct to PTCA in the two per cent of cases where PTCRA is deemed relevant, would be expected to cost the health system less than an additional $2 million per year. To counter this added expense, PTCRA is estimated to save the health system, at best, $1.9 million when used in lesions refractory to PTCA or as an alternative to CABG for single-vessel disease. However, these cost savings may be misleading since the proportion of single-vessel CABG procedures able to be converted to PTCRA is not known. Therefore, costs referred to here should be considered indicative only.

Recommendations

MSAC recommended that on the evidence pertaining to percutaneous transluminal coronary rotational atherectomy (PTCRA):

1) Public funding is supported for the following specific indications:

   a) For revascularisation of complex and heavily calcified coronary artery lesions which cannot be treated by percutaneous transluminal coronary angioplasty (PTCA) alone or when previous PTCA attempts have not been successful; and

   b) For revascularisation of complex and heavily calcified coronary artery stenoses where coronary artery bypass graft (CABG) surgery is contra-indicated.

2) Public funding is not supported for the following indications:

   a) For revascularisation of coronary artery stenoses which can be satisfactorily treated by PTCA alone, with or without stent placement; and

   b) For revascularisation of coronary artery in-stent restenoses as a result of prior coronary artery intravascular interventions (since no long-term data exist and short-term data are conflicting).

The Minister for Health and Ageing accepted this recommendation on 17 September 2002.

Introduction

The Medical Services Advisory Committee (MSAC) has reviewed the use of percutaneous transluminal coronary rotational atherectomy, an intravascular device for complex lesions of the coronary arteries. MSAC evaluates new health technologies and procedures for which funding is sought under the Medicare Benefits Scheme in terms of their safety, effectiveness and cost-effectiveness, while taking into account other issues such as access and equity. MSAC adopts an evidence-based approach to its assessments, based on reviews of the scientific literature and other information sources, including clinical expertise.

MSAC's terms of reference and membership are at Appendix A. MSAC is a multidisciplinary expert body, comprising members drawn from such disciplines as diagnostic imaging, pathology, surgery, internal medicine and general practice, clinical epidemiology, health economics and health administration.

This report summarises the assessment of current evidence for percutaneous transluminal coronary rotational atherectomy.

Background

Atherosclerotic lesions of the coronary arteries

Despite improvements in the fields of medical technology and pharmacology, cardiovascular disease continues to be Australia's leading cause of morbidity and mortality. Cardiovascular disease is the collective grouping of the following six diseases: coronary heart disease, stroke, heart failure, peripheral vascular disease, abdominal aortic aneurysm and acute rheumatic fever and rheumatic heart disease (AIHW 2000).

One of the main underlying problems in cardiovascular disease is atherosclerosis, a process characterised by the accumulation of cells, matrix fibres, lipids and tissue debris in the arterial lumen. This can lead to obstruction of blood flow or ulceration, embolisation and thrombosis (Rutherford 2000). It is most serious when it affects the blood supply to the heart (causing angina, heart attack or sudden death) or to the brain (which can lead to a stroke).

In an attempt to standardise the definition of these types of blockages, the American Heart Association has produced an histological classification system for atherosclerotic lesions (Stary *et al.* 1995). These are summarised in Table 1.

Table 1 Terms used to designate different types of human atherosclerotic lesions in pathology

Lesion Classification	Terms Used in Histologic Classification
I	Initial lesion
IIa	Progression-prone type II lesion
IIb	Progression-resistant type II lesion
III	Intermediate lesion (preatheroma)
IV	Atheroma
Va	Fibroatheroma
Vb	Calcific lesion
Vc	Fibrotic lesion
VI	Lesion with surface defect and/or haematoma/haemorrhage and/or thrombotic deposit

A classification for coronary artery stenoses has also been proposed jointly by the American Heart Association (AHA) and the American College of Cardiology (ACC) (Ellis *et al.* 1990). They have designated three classifications according the characteristics described below in Table 2.

Table 2 American Heart Association / American College of Cardiology Task Force stenosis characteristic classification (Ellis *et al.* 1990)

Type A lesions	
Discrete (<10 mm length)	Little or no calcification
Concentric	Less than totally occlusive
Readily accessible	Not ostial in location
Non-angulated segment, <45°	No major branch involvement
Smooth contour	Absence of thrombus
Type B lesions	
Tubular (10 to 20 mm length)	Moderate to heavy calcification
Eccentric	Total occlusion< 3 months old
Moderate tortuosity of proximal segment	Ostial in location
Moderately angulated segment, >45°, <90°	Bifurcation lesions requiring double guide wires
Irregular contour	Some thrombus present
Type C lesions	
Diffuse (>2 cm length)	Total occlusion >3 months old
Excessive tortuosity of proximal segment	Inability to protect major side branches
Extremely angulated segments >90°	Degenerated vein grafts with friable lesions

Rotational atherectomy: the procedure

Percutaneous transluminal coronary rotational atherectomy (rotational atherectomy or PTCRA) is one of the newer cardiac interventional devices introduced to treat coronary artery stenoses by myocardial revascularisation. Like all coronary procedures, the technology has the ability to relieve or remove some of the symptoms, but cannot actually cure the underlying disease that has caused the formation of these plaques.

Rotational atherectomy was devised to improve upon existing percutaneous coronary revascularisation procedures. Rather than increasing luminal diameter by arterial stretching and plaque fracture as with balloon angioplasty, PTCRA debulks atherosclerotic plaque with an abrasive, diamond-coated burr (Dill & Hamm 1997).

Rotational atherectomy debulks plaque and calcified lesions by reducing them to small particles (approximately 5μm) that pass into the capillary circulation where they are thought to be scavenged by the reticuloendothelial system. The device itself consists of a brass burr coated with diamond chips measuring 30 to 120μm in diameter and welded to a drive shaft. A burr of appropriate size is selected to match the diameter of the vessel being treated. On rotation, the burr selectively removes hard tissue, with soft tissue being deflected by the elastic recoil of normal segments of vessel.

Rotational atherectomy in Australia is usually performed in a tertiary setting by a qualified cardiologist with an interest and experience in PTCRA. The procedure takes

approximately 20 minutes once the PTCRA equipment has been set up and the appropriate guidewire passed through the stenosis under fluoroscopic guidance.

Intended purpose

Rotational atherectomy is intended for patients suffering from coronary artery lesions requiring revascularisation. Most patients referred for coronary revascularisation have significant functional disability. This evaluation examines the role of adjunctive PTCRA for coronary revascularisation with particular reference to non-complex lesions, complex coronary lesions, in-stent restenosis and lesions refractory to or contraindicated for coronary angioplasty.

Clinical need and burden of disease

Coronary heart disease is Australia's greatest health problem. It was responsible for 29 per cent of all deaths in Australia in 1999 (AIHW 2000). In 1993/94, data showed that cardiovascular disease accounted for the largest financial burden on the health care system – $3.9 billion or 12.5 per cent of total health system costs. Cardiovascular disease accounted for 22 per cent of disease burden in Australia in 1996, 33.1 per cent of premature mortality and 8.8 per cent of years of equivalent "healthy" life lost through disease, impairment and disability (AIHW 2000). Coronary heart disease is also the largest cause of cardiac-related hospital admissions for both males and females. Those aged over 55 years are at the greatest risk of admission regardless of their cardiac condition or gender.

Coronary artery bypass graft (CABG) surgery was first performed in Australia in 1970. Its use has grown since inception, particularly in the last two decades. While the majority of all CABG procedures bypass blockages or lesions within the coronary arteries, CABG surgery often needs to be performed when lesions previously treated with other modalities, such as angioplasty, develop restenosis. In Australia in 1998, 76 cardiac surgeons operating in 50 units throughout Australia, performed 17,448 CABG procedures (Davies & Senes 2001).

Percutaneous transluminal coronary angioplasty (PTCA) was introduced as a treatment option to Australian cardiac surgeons in the early 1980s. The use of PTCA has increased as minimally invasive surgical options become increasingly available to treat atherosclerotic lesions. Stenting was the third major cardiac intervention to be introduced a decade later in the early 1990s. As with the other two modalities, the use of stents has increased greatly since their introduction. In Australia in 1999, stents were inserted into 92 per cent of patients undergoing PTCA. That same year, 122 cardiologists, operating in 57 interventional cardiology units throughout Australia, performed 19,444 PTCA procedures (Davies & Senes 2002).

In addition to the adjunctive use of stents with PTCA, adjunctive ablative modalities, known collectively as atherectomy, are used when appropriate. These include directional coronary atherectomy, extraction coronary atherectomy, percutaneous transluminal coronary rotational atherectomy (PTCRA) and laser techniques. In Australia in 1999, cardiologists trained in PTCRA performed a total of 260 PTCRA procedures (Davies & Senes 2002).

Recent figures (de Looper & Bhatia 2001) indicate the annual number of CABG procedures is reaching a plateau of about 17,500 per year after rising during the late 1980s and early 1990s. The annual number of PTCA procedures has been rising in a linear fashion since 1988 while those for stent implantation have been rising exponentially since 1993. These trends are shown in Figure 1 and Table 3.

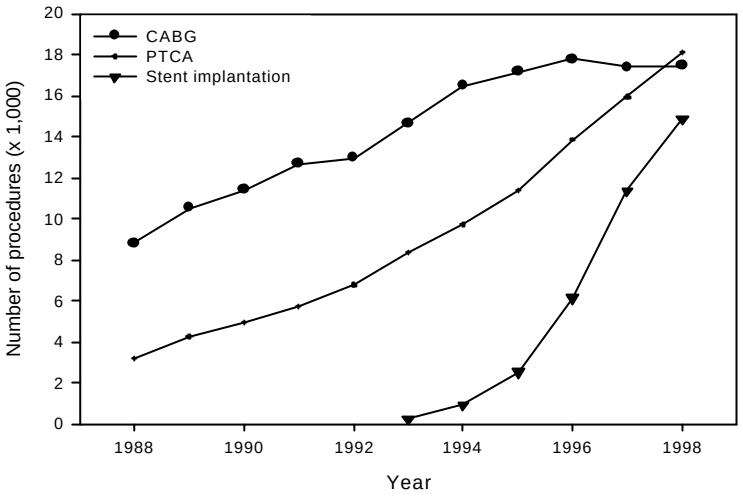

Figure 1 Procedures for coronary heart disease 1988–1998 (de Looper & Bhatia 2001).

Table 3 Procedures for coronary heart disease 1988–1998 (de Looper & Bhatia 2001).

	1988	1989	1990	1991	1992	1993	1994	1995	1996	1997	1998
CABG	8,786	10,531	11,381	12,649	12,935	14,638	16,465	17,150	17,759	17,377	17,448
PTCA	3,153	4,219	4,904	5,726	6,748	8,334	9,732	11,348	13,853	15,918	18,094
Stent use	-	-	-	-	-	255	896	2,517	6,146	11,361	14,838

* Abbreviations: CABG=coronary artery bypass graft; PTCA=percutaneous transluminal coronary angioplasty.
† The following ICD-9-CM codes were used: CABG, 36.1; PTCA, 36.01, 36.02, 36.06, 36.07; Stent implantation, 36.06, 36.07.

The proportion of PTCA procedures that involve stent implantation have been steadily increasing since 1993 (Figure 2).

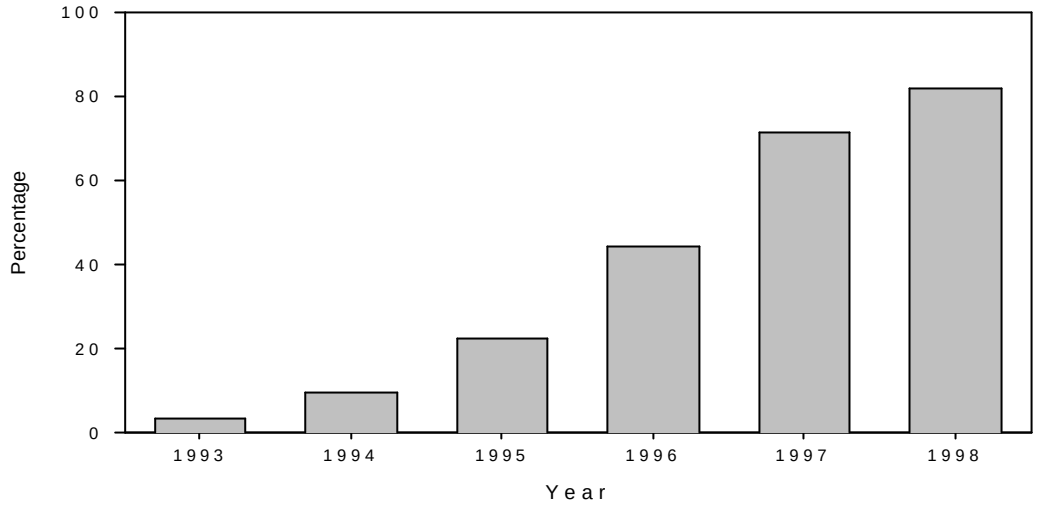

Figure 2 Percentage of percutaneous transluminal coronary angioplasty involving stent implantation, 1993-1998 (de Looper & Bhatia 2001).

In contrast, both the absolute number and proportion of atherectomies (including PTCRA and other modalities, Table 4) have been variable although there is the potential for large increases (Senes & Davies 1999, Davies & Senes 2001).

Table 4 Frequency distribution of rotational atherectomy procedures, 1993-1996, 1998-1999 (Senes & Davies 1999, Davies & Senes 2001, Davies & Senes 2002)**.***

Year	PTCRA		All Atherectomies†	
	Frequency	Percentage of all PTCA	Frequency	Percentage of all PTCA
1993	117	1.4	195	2.3
1994	167	2.0	255	3.1
1995	132	1.5	159	1.8
1996	147	1.5	153	1.6
1997	-	-	-	-
1998	358	3.4	365	3.4
1999	260	2.0	272	2.1

*Abbreviations: PTCRA=percutaneous transluminal coronary rotational atherectomy;
PTCA=percutaneous transluminal coronary atherectomy.
† Includes directional atherectomies and transluminal extraction catheters.

Estimates of the number of revascularisation procedures claimed under the Medicare Benefits Scheme for calendar years 1997 to 2000 are shown in Table 5.

Table 5 Myocardial revascularisation techniques - Medicare Benefits Schedule services rendered 1997–2000 (HIC 2001).

Item number	Item description	Number of Medicare Benefits Schedule services			
		1997	1998	1999	2000
35304	Transluminal balloon angioplasty of 1 coronary artery, percutaneous or by open exposure.	2,100	1,477	1,269	1,101
30305	Transluminal balloon angioplasty of more than 1 coronary artery, percutaneous or by open exposure.	233	134	110	115
35310	Transluminal stent insertion including associated balloon dilatation for coronary artery, percutaneous or by open exposure, excluding associated radiological services and preparation, and excluding aftercare.	5,480	7,305	8,044	9,473
38496	Artery harvesting (other than internal mammary), for coronary artery bypass	2,264	2,656	2,457	2,653
38497	Coronary artery bypass using saphenous vein graft or grafts only, including harvesting of vein graft material where performed	945	816	700	601
38500	Coronary artery bypass using single arterial graft, with or without vein graft or grafts, including harvesting of internal mammary artery or vein graft material where performed	3,765	3,196	3,172	2,965
38503	Coronary artery bypass using 2 or more arterial grafts, with or without vein graft or grafts, including harvesting of internal mammary artery or vein graft material where performed	2,785	3,071	2,858	3,005

Existing procedures and comparators

The choice of intervention for coronary artery disease varies according to: lesion type and location; operator skill, preference and availability; and the ability of a patient to cope with a particular treatment. Many of the devices or procedures are often used at the same time according to the severity and location of the occluded arteries. Two of the most dominant forms of therapy for myocardial revascularisation in Australia have been CABG and PTCA. This review compares PTCRA to PTCA alone and with CABG.

Coronary artery bypass grafting

Coronary artery bypass grafting (CABG) is a procedure where a section of vein, artery or synthetic tube is grafted between the aorta and a coronary artery distal to an obstructive lesion in its lumen. The two most common conduits used are the greater saphenous vein and the internal mammary artery. The conduit used depends on several factors including patient age, health status and location of the blockage. Figure 3 shows how these different conduits are placed. While the average number of grafts that patients receive is 3.0, only 3.85 per cent of patients are receiving CABGs for a single coronary artery blockage without a concomitant procedure (Davies & Senes 2001).

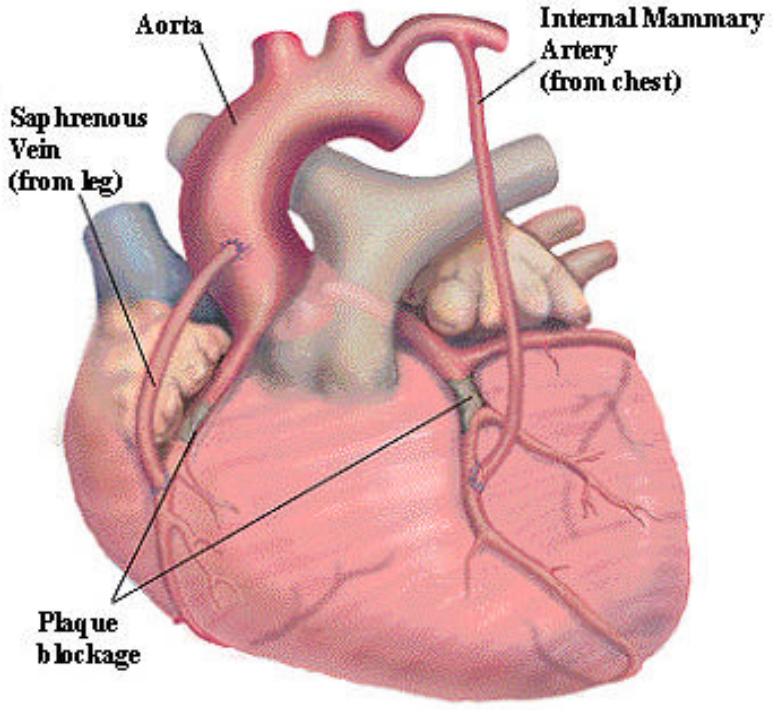

Figure 3 **Use of conduits in coronary artery bypass surgery (Illustration by Mitchell Christensen, reprinted with permission from ViaHealth).**

Percutaneous transluminal coronary angioplasty

Percutaneous transluminal coronary angioplasty (PTCA) is currently one of the most common minimally-invasive coronary procedures currently being performed in Australia and, as such, was selected as one of the comparators for this study. PTCA involves inserting a catheter with a balloon into a major artery via the skin. The catheter is threaded through the circulation back towards the heart and into the coronary arteries to the area of the vessel blockage. The balloon is then inflated against the plaque to create a wider passage for blood flow (Davies & Senes 2001). Contraindications to angioplasty include proximal left anterior descending lesions, left main disease, long segments of disease which would be difficult to get a balloon catheter across, chronic occlusions, circumferential lesions, heavily calcified lesions, bifurcations and the appearance of liquid cholesterol which may embolise (Baumgartner 1999).

Stent placement

The two main categories of stents are balloon-expandable and self-expandable. Balloon-expandable stents are of rigid stainless steel crimped onto an angioplasty balloon and deployed by balloon inflation. The self-expanding model is deployed by passing the delivery catheter over a guide wire and withdrawing a covering sheath (Schneider 1998). The delivery of the stent to the stenosed site is identical to that used in balloon angioplasty.

Transluminal extraction catheter

The transluminal extraction catheter (TEC) is a percutaneously-introduced flexible tube that tracts over a steerable 0.014-inch guide wire and through a 10.5F guiding catheter to the coronary artery lesion (Pavlides *et al.* 1992). Like the PTCRA system, the TEC is non-occlusive, working by rotational cutting without balloon inflation.

Directional coronary atherectomy

Directional coronary atherectomy (DCA) is a technique by which a catheter with a small mechanically-driven cutter shaves plaque and stores it in a collection chamber. The plaque is then removed from the device when it is withdrawn.

Like the PTCRA system, DCA allows for the differential cutting of atherosclerotic lesions from coronary arteries. Directional atherectomy can be used as a stand-alone procedure or as an adjunct to balloon angioplasty or other related procedures. In common with other catheter based intervention systems, the DCA catheter is introduced via the right or left femoral artery depending upon the target area in the heart.

Local intracoronary radiotherapy (brachytherapy)

Intracoronary radiotherapy involves treating coronary stenosis with a radioactive source from within the artery (Sheppard & Eisenberg 2001). The radiation is believed to inhibit the cellular proliferation that causes obstruction of the vessel. The implantation of a radioactive stent and the catheter-based delivery of radioactive seeds are two of the available techniques (Sheppard & Eisenberg 2001). The United States' FDA has recently

approved two devices for the delivery of radiation to coronary arteries but only for use after percutaneous revascularisation of coronary arteries with in-stent restenosis, using a catheter-based delivery method (Sapirstein *et al.* 2001).

Marketing status of the device

The Therapeutic Goods Administration (TGA) has listed Boston Scientific Corporation's rotational atherectomy device (Rotablator®) and console under AUST L53295 and the burr under AUST L53286.

Current reimbursement arrangement

There is currently no specific Medicare Benefits Schedule (MBS) item number for PTCRA.

Approach to assessment

Review of literature

This review applies techniques derived from the National Health and Medical Research Council (NHMRC 2000), the Cochrane Collaboration (Clarke & Oxman 2000), the Quality of Reporting of Meta-analysis (QOROM) group (Moher *et al.* 1999) and the Centre for Reviews and Dissemination at the University of York (Kahn *et al.* 2001).

The evaluation sought to answer the following questions:

- What is the evidence for safety of PTCRA compared to PTCA?
- In patients with non-complex lesions of the coronary arteries, what is the evidence for effectiveness of percutaneous transluminal coronary rotational atherectomy (PTCRA) compared to percutaneous transluminal coronary angioplasty (PTCA)?
- What is the evidence for effectiveness of PTCRA compared to PTCA in patients with complex lesions of the coronary arteries defined by presence of calcified, bifurcation, ostial, or long or diffuse lesions, and chronic total occlusions?
- What is the evidence for effectiveness of PTCRA compared to PTCA in patients with lesions arising from in-stent restenosis?
- What is the evidence for effectiveness of PTCRA in patients with lesions refractory to PTCA?
- If an adequate profile of the safety and effectiveness of the procedure is determined, what is the evidence for the cost-effectiveness of i) PTCRA compared to PTCA in general and within the identified subgroups; and ii) PTCRA in patients with lesions refractory to PTCA?
- What is the evidence for effectiveness and cost-effectiveness of PTCRA compared to CABG surgery?

The primary outcome measures of interest were restenosis rates at specific durations of follow-up of at least six months and the incidence of major adverse cardiac events (MACE) including death, Q-wave myocardial infarction (MI) and emergency surgery.

Lesion complexity was defined according to the modified AHA/ACC criteria. Type A lesions were classified as non-complex lesions. Type B_1, B_2 or C lesions were classified as complex lesions. Chronic total occlusions (complete blockage of flow in an artery for longer than three months) are Type C lesions according to the criteria.

Literature search

The biomedical literature was searched to identify relevant studies and reviews for the period between 1966 to March 2001. Table 6 lists the electronic databases accessed in the search.

Table 6 Electronic databases (including edition) accessed in the review.

Database	Period Covered
Best Evidence (Ovid)	1991 to January/February 2001
Biological Abstracts (Ovid)	1980 to December 2000
CINAHL (Ovid)	1982 to February 2001
Cochrane Library including: the Cochrane Database of Systematic Reviews, the Database of Abstracts of Reviews of Effectiveness, the Cochrane Controlled Trials Register, Health Technology Assessment Database, and the NHS Economic Evaluation Database	Issue 1, 2001
Current Contents (Ovid)	1993 Week 26 to 2001 Week 14
EMBASE (Ovid)	1980 to 2001 Week 10
HealthSTAR	1975 to March 2001
Medline (Ovid)	1966 to December 2000
National Guidelines Clearinghouse	March 2001

A sensitive search strategy was applied in order to widen the selection of potentially relevant articles, with the expectation of an increase in the number of potentially irrelevant articles identified by the strategy (Haynes *et al.* 1994a, Haynes *et al.* 1994b). A search strategy was parsimoniously derived from numerous pilot searches of the electronic literature and refined iteratively. The final strategy is shown in Table 7.

Table 7 Refined search strategy and its implementation in selected electronic databases.*

Strategy	Database
((atherectom$ AND rotat$).mp OR (rotablat$.mp))	Ovid databases
((atherectom* AND rotat*) OR rotablat*)	Cochrane Library
((CABG OR bypass) AND (rotablat$.mp))	Ovid databases
((CABG OR bypass) AND (rotablat*))	Cochrane Library

* Electronic databases apply different characters as "wildcard" symbols. These symbols refer to characters or groups of characters that appear in the terminus of a word fragment. For the Ovid databases, the wildcard character is the dollar sign ("$"); the Cochrane Library uses the asterisk ("*"). In this case, "atherectom$" expands to "atherectomy", "atherectomies", etc.

Electronic searching included the Internet sites of health technology assessment groups (listed in Appendix D), professional medical organisations, medical centres, health service providers and relevant national and international government agencies. Data provided by the manufacturer of the device were included where relevant, but confirmation of the information was sought from independent sources.

Textbooks and book chapters were assessed, as were conference proceedings and collections of abstracts. Reference lists of publications were scanned and relevant citations retrieved. Where feasible or necessary, authors were contacted to provide additional information.

Entry criteria

Collected citations were filtered through a multi-level review involving a team with skills in clinical medicine, public health, health informatics, basic science, clinical epidemiology and biostatistics. Articles were excluded if they met the following criteria:

- Pre-clinical studies involving *in vitro* experiments, animals, isolated human organs or cadavers;
- Focus of the study was not rotational atherectomy for lesions of the coronary arteries in the context of a comparative design (e.g. studies using the technology on the peripheral vasculature);
- Studies enrolling less than 10 subjects;
- Case reports or case series if higher-level evidence is available;
- Non-systematic reviews, opinions published as editorials to letters to the editor and descriptive studies; and
- Articles that included data published in later studies.

No restrictions were placed on dates, languages, publication types or population characteristics.

Review profile

A total of 586 studies were identified by the search. Of these, 219 (37.4 per cent) were excluded on the basis of the criteria previously defined. The remaining 367 articles were retrieved for more detailed evaluation. These included articles that did not provide enough preliminary information to make a decision about inclusion or exclusion (i.e. due to an unclear or missing abstracts, uninformative titles, etc.). Detailed evaluation of articles necessitated assessment of the full text. A final decision about entry was made by consensus between two independent reviewers.

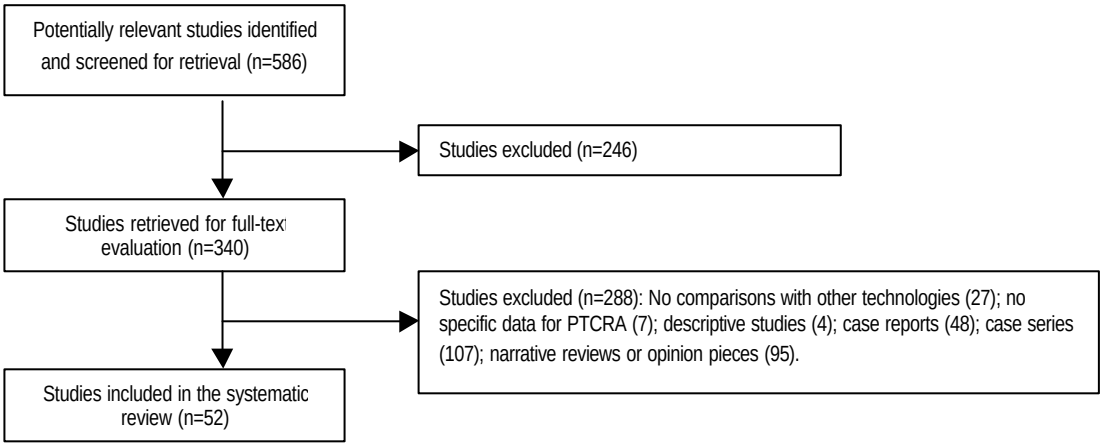

Figure 4 **Flow diagram summarising the results of the literature search and the application of entry criteria.**

Of the 367 citations requiring full text assessment, 315 (85.8 per cent) were excluded. These studies are listed in Appendix E. The remaining 52 studies provide the basis of this review. Study flow is described in Figure 4.

Data extraction

The review extracted data from the included articles using a standardised instrument created for this assessment. In some cases, quantitative information was poorly presented. In these instances, every effort was made to apply statistical techniques to derive estimates of effect size or variability if enough information was available. Otherwise, a statement indicating the paucity of primary information was made. Two independent reviewers examined each article. Discrepancies in evaluation were discussed and resolved through consensus.

Dimensions of evidence

The NHMRC recommends that evidence assessment move toward an evaluation of specific "dimensions" (NHMRC 2000). These dimensions (Table 8) consider important aspects of the evidence supporting a particular intervention and include three main domains: strength of the evidence, size of the effect and relevance of the evidence. The first domain is derived directly from the literature identified as informing a particular intervention. The last two require expert clinical input as part of its determination.

Table 8 Evidence dimensions (NHMRC 2000)

Type of evidence	Definition
Strength of the evidence:	
Level	The study design used, as an indicator of the degree to which bias has been eliminated by design.*
Quality	The methods used by investigators to minimise bias within a study design.
Statistical precision	The *p*-value or, alternatively, the precision of the estimate of the effect. It reflects the degree of certainty about the existence of a true effect.
Size of effect	The distance of the study estimate from the "null" value and the inclusion of only clinically important effects in the confidence interval.
Relevance of evidence	The usefulness of the evidence in clinical practice, particularly the appropriateness of the outcome measures used.

* See Table 9.

The strength of the evidence is composed of three sub-domains. Previous assessments concentrated only on the first of these, the level of evidence (NHMRC 1999). Table 9 lists the designations recommended by the NHMRC.

Table 9 Designations of levels of evidence (NHMRC 2000)*

Level of Evidence	Study Design
I	Evidence obtained from a systematic review of all relevant randomised controlled trials.
II	Evidence obtained from at least one properly-designed randomised controlled trial.
III-1	Evidence obtained from well-designed pseudorandomised controlled trials (alternate allocation or some other method).
III-2	Evidence obtained from comparative studies (including systematic reviews of such studies) with concurrent controls and allocation not randomised, cohort studies, case-control studies, or interrupted time series with a control group.
III-3	Evidence obtained from comparative studies with historical control, two or more single arm studies, or interrupted time series without a parallel control group.
IV	Evidence obtained from case series, either post-test or pre-test/post-test.

* Modified from NHMRC (1999).

The assessment of quality, another important sub-domain, was based on characteristics known to reflect important aspects of study design (Schulz *et al.* 1995, Jadad *et al.* 1996). Table 10 summarises these characteristics and the ordinal scale used in the assessment.

Table 10 Study design characteristics used to assess the methodologic quality

Randomisation	
Adequate	Method of allocation is random, such as computer-generated number sequences and tables of random numbers.
Unclear	Trials in which the authors failed to describe the method of randomisation with enough detail to determine its validity.
Inadequate	Method of allocation is non-random, such as alternation methods or the use of case numbers.
Concealment of allocation	
Adequate	Adequate measures to conceal allocations such as central randomisation; serially numbered, opaque, sealed envelopes; or other descriptions that contain convincing elements of concealment.
Unclear	Unclearly concealed trials in which the author failed to describe the method of concealment with enough detail to determine its validity.
Inadequate	Method of allocation is not concealed.
Masking	Masking strategy applied (single, double, etc.).
Participant inclusion	Intention to treat analysis was performed.
Losses to follow-up	Losses specified.

Assessment of heterogeneity

The review used a two-stage process to examine the heterogeneity of treatment effects. Firstly, the clinical and epidemiological attributes were examined to establish whether they were sufficiently similar to justify statistical pooling. If this was the case, the second stage of assessment of heterogeneity moved on to statistical analysis. The review used the Cochran Q statistic (Cochran 1954) to test the hypothesis that the reported treatment effects for each indication were equal. The Q statistic is known to have low power in detecting heterogeneity (Boissel *et al.* 1989). For this reason, the review specified a Type I error rate (the probability of detecting a difference when one is not present) of ten per cent (α=0.10) for this test (Fleiss 1986). All statistical analyses were performed using STATA version 7.0 (Stata Corporation, College Station, Texas, USA).

Conduct of meta-analysis

When the degree of homogeneity was acceptable on statistical and clinical grounds, summary estimates of odds ratios and weighted mean differences was derived using a random-effects model (DerSimonian & Laird 1986). The review checked the robustness of the summary estimate by performing sensitivity analyses. Standard statistical convention was followed and a Type I error rate was assumed for all analyses at five per cent (α=0.05). Results are presented in means (standard deviations [SD]) or frequencies (percentages), as noted.

Expert advice

A supporting committee with expertise in interventional cardiology, vascular surgery, cardiac surgery, internal medicine, general practice and consumer issues was established to evaluate the evidence and provide advice to MSAC from clinical and health consumer perspectives. In selecting members for supporting committees, MSAC's practice is to approach the appropriate medical colleges, specialist societies and associations for nominees. Membership of the supporting committee is provided at Appendix B.

Results of assessment

Is it safe?

The difficulty of estimating the incidence of complications following PTCRA is due to the paucity of information from well-designed, long-term prospective cohort studies or randomised controlled trials. Case series that report the experience of single centres have limited value given the unquantifiable, but potentially substantial, problems of strong selection bias, unclear catchment areas, limited sample sizes and variations in the definitions used (Kaufmann & Meyer 1995).

Registries are now being established as central repositories for specific information about all procedures occurring within a geographic area. This is a positive development but does not totally rule out the presence of these methodological problems. Some information has been derived from such registries. The New Approaches to Coronary Intervention (NACI) registry is sponsored by the US National Heart, Lung, and Blood Institute (NHLBI) and has demonstrated the potential for such databases to generate hypotheses that may be tested in subsequent trials (Baim *et al.* 1994). Industry-sponsored registries are also available (Stertzer *et al.* 1993, Reisman & Buchbinder 1994).

Rotational atherectomy is associated with similar complications as those seen in other interventional cardiology procedures. Vasospasm involving the coronary arteries, which may manifest as transient ischaemic chest pain (with or without electrocardiographic changes), occurs often.. During procedures that involve the right coronary, circumflex and ostial left anterior descending arteries, other potential complications may occur including bradycardia, atrioventricular block or asystole (Reisman & Buchbinder 1994, Ramsdale *et al.* 1995). In-stent restenosis is another complication which may lead to a poorer safety outcome.

As with standard interventional cardiology procedures, safety issues regarding PTCRA are most likely to become evident within 24 hours of the procedure. Because of this, one should consider whether the major adverse cardiac events (MACE), discussed below, represent: a) safety aspects of PTCRA if they do not occur within the first 24 hours of the procedure; or b) outcomes associated with underlying cardiac disease and treatment with interventional procedures. Outcomes examined more than one week after PTCRA are unlikely to be related to the procedure itself and most likely are associated with underlying pathology, comorbidity or tissue response to the procedure itself (e.g. similar to restenosis following standard angioplasty).

The evidence presented and discussed below examines MACE in relation to extended hospital stay until discharge. Some caution should be exercised when considering whether or not the types of MACE assessed are relevant to the safety aspects of the PTCRA procedure.

Evidence from randomised controlled trials

Major adverse cardiac events

Major adverse cardiac events defined as myocardial infarction, emergency CABG or death were reported by all studies as in-hospital events (Table 11) and by a subset during follow-up (Table 13).

Table 11 Incidence of in-hospital major cardiac adverse events (MACE) in trials examining the effectiveness of PTCRA with adjunctive PTCA versus PTCA alone.*

Study	PTCRA-PTCA					PTCA Alone				
	MI	Emergency CABG	Death	Comb MACE	Total No. of Subjects	MI	Emergency CABG	Death	Comb MACE	Total No. of Subjects
Buchbinder *et al.* 2000	---	---	---	29	170	---	---	---	27	194
Dill *et al.* 2000	6	6	1	---†	252	4	3	4	---†	250
Eltchaninoff *et al.* 1997	0	0	0	0	26	1	0	0	1	26
Reifart *et al.* 1997	3	2	2	7	231	4	1	2	6	222
Reisman *et al.* 1997‡	---	---	---	3	222	---	---	---	0	220
Guerin *et al.* 1996	1	0	0	---†	32	1	2	0	---†	32
Danchin *et al.* 1995	0	1	0	1	50	0	0	0	0	50

* Abbreviations: CABG=coronary artery bypass grafting; MACE=major adverse cardiac events; MI=myocardial infarction; PTCA=percutaneous transluminal coronary angioplasty; PTCRA=percutaneous transluminal coronary rotational atherectomy; comb = combined.

† Not reported as a composite end point.

‡ Omitted in statistical summaries of safety due to heterogeneity in population characteristics.

As a composite end point, MACE was reported by five studies (Danchin *et al.* 1995, Eltchaninoff *et al.* 1997, Reifart *et al.* 1997, Reisman *et al.* 1997, Buchbinder *et al.* 2000). The study by Reisman *et al.* (1997) was omitted due to the heterogeneity of the study population. Rotational atherectomy with adjunctive angioplasty was not associated with a statistically significant increase in the risk of in-hospital MACE compared to angioplasty alone (risk ratio [RR]=1.20; 95% confidence interval [CI]=0.78, 1.85; p=0.410; Figure 5). No substantial statistical heterogeneity was detected (Q=0.98; df=3; p=0.807).

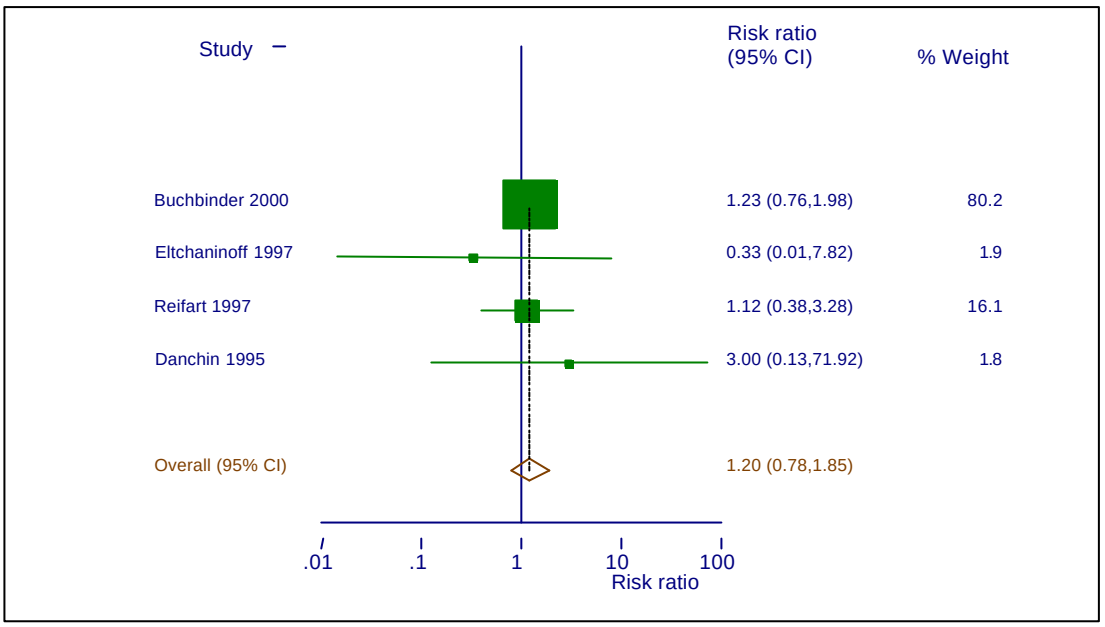

Figure 5 **Risk of major adverse cardiac events during the in-hospital period in patients receiving PTCRA with adjunctive PTCA versus PTCA alone.**

Aspects of MACE were separated in order to determine whether the technology was preferentially affecting a particular outcome. The definition of myocardial infarction used in each of the studies is shown in Table 12. All three studies (Danchin *et al.* 1995, Reifart *et al.* 1997, Dill *et al.* 2000) that defined the event used a definition with at least two components: serum creatine kinase and electrocardiographic findings. Reifart *et al.* (1997) and Danchin *et al.* (1995) both required a rise in creatine kinase of twice the normal level while Dill *et al.* (2000) used a level that was three times the normal limit. Danchin *et al.* (1995) also included prolonged chest pain in the definition. Eltchaninoff *et al.* (1997) and Guerin *et al.* (1996) failed to specify the definition of the end-point used.

Table 12 **Definitions of myocardial infarction used in trials examining the effectiveness of PTCRA with adjunctive PTCA versus PTCA alone.**

Study	Definition of Myocardial Infarction
Dill *et al.* 2000	Rise in creatine kinase of more than three times the normal limit in the presence of Q waves.
Eltchaninoff *et al.* 1997	Not stated. Standard 12-lead electrocardiogram and serial measurement of total and MB fraction of creatine kinase was performed while in hospital.
Reifart *et al.* 1997	New Q waves in two or more contiguous leads and a creatine kinase elevation of two or more times the upper limit of normal and/or elevated creatine kinase-MB fraction to at least twice the upper limit of normal.
Guerin *et al.* 1996	Not stated. Electrocardiographic descriptors used.
Danchin *et al.* 1995	At least two of: 1) chest pain of prolonged (>20 minutes) duration; 2) new ST-segment elevation or depression (>1 mm in ≥2 leads) or Q wave on the post-procedural electrocardiogram; and 3) an increase in creatine kinase values greater than twice the upper limit of normal.

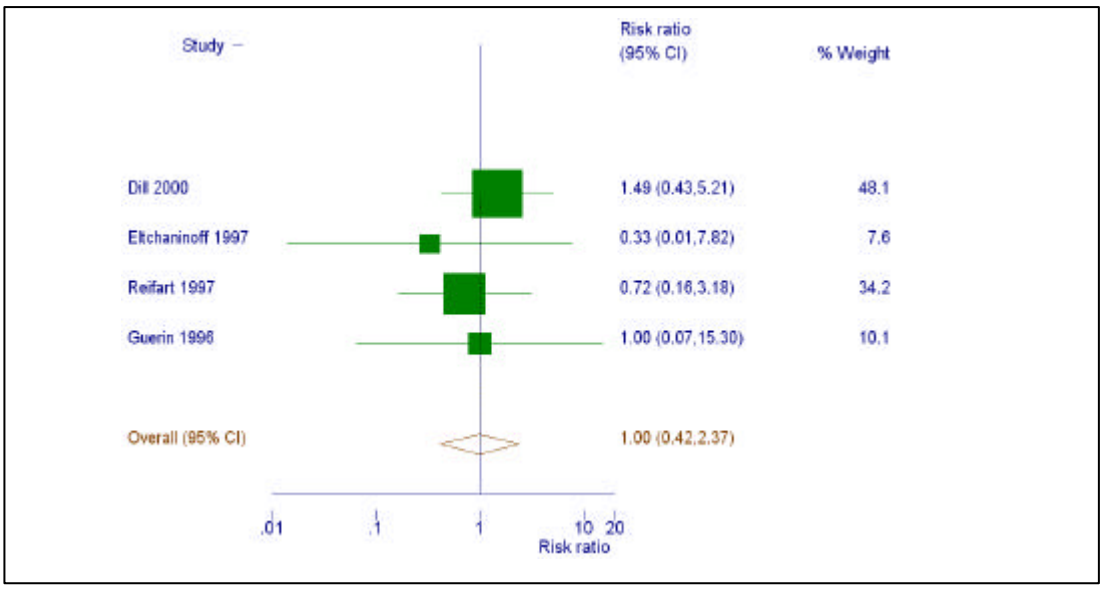

Figure 6 **Risk of myocardial infarction in the in-hospital period in patients receiving PTCRA with adjunctive PTCA versus PTCA alone.**

Assuming there is little clinical dissimilarity in the variations in the definitions used, the estimate of the pooled effect shows no statistically significant differences in the rates of myocardial infarction between the two groups (RR=1.00; 95% CI=0.42, 2.37; p=0.993; Figure 6) with no statistically significant heterogeneity present (Q=1.04; df=3; p=0.792). Results from Danchin *et al.* (1995) were excluded because no outcomes were reported.

Rotational atherectomy with adjunctive PTCA was associated with a non-statistically significant 56 per cent increase in the risk of emergency CABG during the in-hospital period compared to PTCA alone (RR=1.56; 95% CI=0.55, 4.44; p=0.405; Figure 7). While statistical heterogeneity was not present (Q=2.15; df=3; p=0.542) the study by Guerin *et al.* (1996) seems to indicate a protective effect induced by the PTCRA-PTCA combination (although, admittedly, the study was small). Analysis excluding this study did not substantially affect the results (data not shown). Results from Eltchaninoff *et al.* (1997) were excluded because no outcomes were reported.

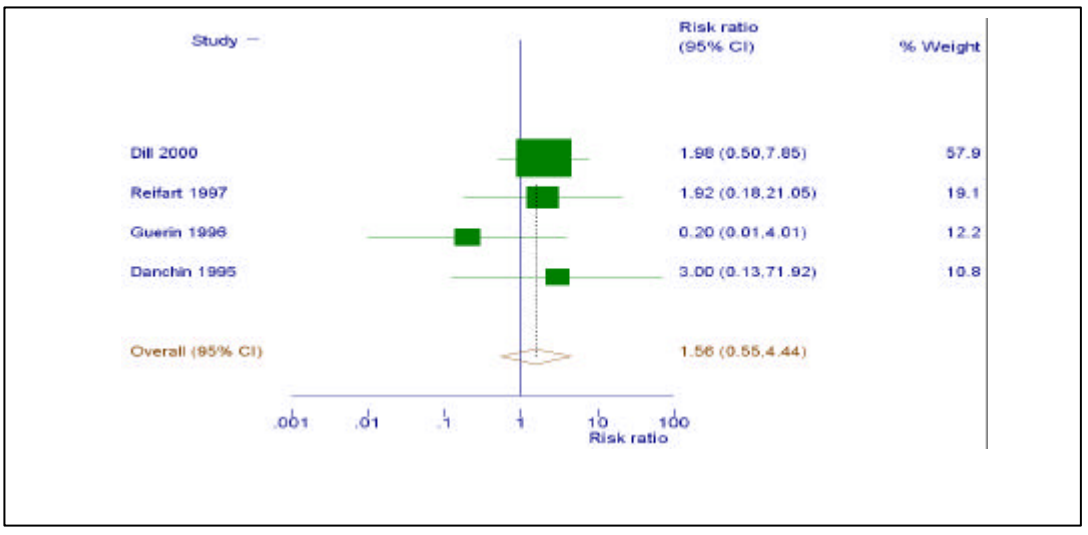

Figure 7 **Risk of emergency CABG in the in-hospital period in patients receiving PTCRA with adjunctive PTCA versus PTCA alone.**

The risk of in-hospital mortality was reduced by about half in the group receiving PTCRA-PTCA compared to those receiving PTCA alone, although the result failed to reach statistical significance (RR=0.53; 95% CI=0.12, 2.26; *p*=0.388; Figure 8).

Trial-specific results for major adverse cardiac events (MACE) at six months of follow-up are presented in Table 13 for the subset of studies that reported these end points. In determining the composite end point MACE, Reifart *et al.* (1997) included the number of repeat surgical and non-surgical interventions. It is unclear whether the authors counted all interventions (which could conceivably occur more than once in a single subject) towards the total or whether an indicator variable was used (to specify the presence of any intervention regardless of the total number received).

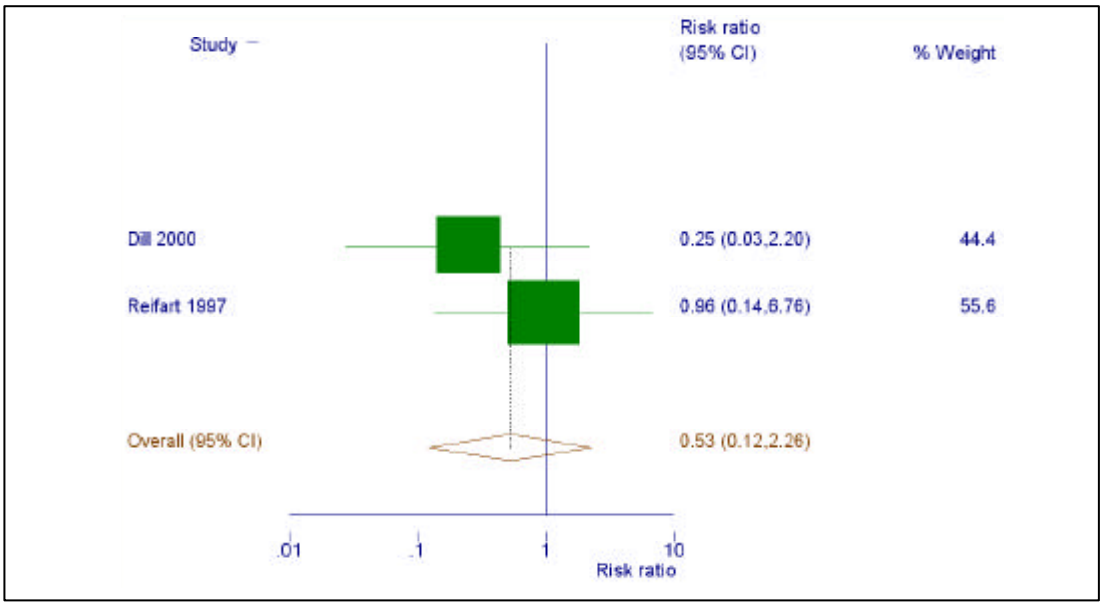

Figure 8 **Risk of death in the in-hospital period in patients receiving PTCRA with adjunctive PTCA versus PTCA alone.**

Table 13 **Incidence of major cardiac adverse events at six months of follow-up in trials examining the effectiveness of PTCRA with adjunctive PTCA versus PTCA alone.***

Study	PTCRA-PTCA					PTCA Alone				
	MI	Emergency CABG	Death	Comb MACE	Total No. of Subjects	MI	Emergency CABG	Death	Comb MACE	Total No. of Subjects
Dill *et al.* 2000	1	9	0	---†	210	0	13	0	---	213
Reifart *et al.* 1997	5	15	5	94‡	205	5	12	7	70‡	191

* Abbreviations: CABG=coronary artery bypass grafting; MACE=major adverse cardiac events; MI=myocardial infarction; PTCA=percutaneous transluminal coronary angioplasty; PTCRA=percutaneous transluminal coronary rotational atherectomy; comb = combined.

† Not reported as a composite end point.

‡ Includes repeat non-surgical and surgical intervention in composite end point.

Rotational atherectomy with adjunctive PTCA was associated with a 25 per cent increase in the risk of major adverse cardiac events at six months (Table 14). The increase was of borderline statistical significance. The incidence of myocardial infarction, emergency CABG and death were not significantly different between the groups, but the point estimate of the last outcome showed some capacity for a protective effect by PTCRA.

Table 14 Estimates of the relative risk of specific outcomes at six months of follow-up in patients receiving PTCRA with adjunctive PTCA versus PTCA alone.*

Outcome	Number of Studies	Risk Ratio		Heterogeneity		
		Point Estimate (95% CI)	*p*-value	Q	df	*p*-value
Myocardial Infarction	2	1.08 (0.34, 3.40)	0.890	0.46	1	0.497
Emergency CABG	2	0.93 (0.54, 1.61)	0.803	0.80	1	0.370
Death	1	0.66 (0.21, 2.06)	0.480	-	-	-
MACE†	1	1.25 (0.98, 1.59)	0.066	-	-	-

* Abbreviations: CABG=coronary artery bypass grafting; CI=confidence interval; df=degrees of freedom; MACE=major adverse cardiac events; Q=Cochran Q statistic for heterogeneity.

† Includes repeat non-surgical and surgical intervention in composite end point.

Patients undergoing PTCRA are nine times as likely to experience a vascular spasm, four times as likely to experience a perforation and about twice as likely to have transient vessel occlusions (Table 15). Both angiographic dissections and the use of stents as a bailout procedure were less common in the group receiving PTCRA. Admittedly, for some outcomes, the 95 per cent confidence intervals of the point estimates include 1.0. However, these same intervals include clinically-relevant risks that would benefit from further investigation.

Table 15 Incidence of adverse events in trials examining the effectiveness of PTCRA with adjunctive PTCA versus PTCA alone.*

Adverse Outcome	Pooled Effect Estimates and Heterogeneity				References
	Risk Ratio (95% CI)	Heterogeneity (Q; df; *p*-value)	Attributable Risk per 100 (95% CI)	Heterogeneity (Q, df, *p*-value)	
Events of primary importance					
Perforation	3.58 (0.59, 21.73)	0.03; 1; 0.872	0.32(-0.46, 1.11)	2.70; 2; 0.259	Dill *et al.* 2000, Reifart *et al.* 1997, Reisman *et al.* 1997
Angiographic Dissection	0.49 (0.33, 0.74)	0.98; 2; 0.612	-6.82(-11.36, -2.28)	2.56; 2; 0.278	Eltchaninoff *et al.* 1997, Reifart *et al.* 1997, Reisman *et al.* 1997
Bailout Stenting	0.38 (0.22, 0.65)	0.57; 2; 0.753	-3.77(-9.77, 2.23)	24.13; 2; <0.001	Dill *et al.* 2000, Reifart *et al.* 1997, Reisman *et al.* 1997
Events of secondary importance					
Vascular Spasms	9.23 (4.61, 18.46)	0.98; 2; 0.614	13.54(5.30, 21.80)	10.31; 2; 0.006	Dill *et al.* 2000, Reifart *et al.* 1997, Guerin *et al.* 1996
"Slow/No Flow"	5.10 (1.69, 15.40)	2.54; 2; 0.281	4.14(-1.49, 9.79)	23.87; 2; <0.001	Dill *et al.* 2000, Reifart *et al.* 1997, Reisman *et al.* 1997
Transient Vessel Occlusion	2.28 (1.00, 5.19)	0.65; 2; 0.721	1.94(-1.12, 5.00)	4.08; 2; 0.130	Dill *et al.* 2000, Eltchaninoff *et al.* 1997, Reifart *et al.* 1997

* Abbreviations: AV=atrioventricular; df=degrees of freedom; MI=myocardial infarction; Q=Cochran Q statistic for heterogeneity.

"Slow flow" or "no flow" is an adverse outcome that is recognised by the reduction or absence of antegrade blood flow distal to a specific segment not attributable to abrupt closure, high-grade stenosis or spasm of the target lesion (Abbo *et al.* 1995). Reisman and Buchbinder (1994) suggested this might be due to a large plaque burden being delivered

to the distal vascular bed by the ablative action of the device. Patients undergoing PTCRA experienced this outcome five-times more often than those undergoing PTCA.

The refinement of technology, the continued development of technique and the use of adjunctive medications have made the presence of vascular spasms, slow/no flow phenomena and transient vessel occlusions manageable or avoidable. Although beyond the scope of this evaluation, results from published studies that have examined procedural aspects of the device (i.e. burr speed, adjunctive drugs, procedural time, etc.) have led to reductions in the severity and incidence of these events.

Evidence from comparative studies

In a prospective design that used angiographically-confirmed cases of no flow, Abbo *et al*. (1995) estimate the incidence of the condition to be about eight in 104 subjects, or about 7.69 per cent (95% CI=3.38, 14.60) for PTCRA compared to 0.32 per cent (95% CI=0.21, 0.45) for PTCA. Of the eight subjects who received PTCRA and who subsequently experienced no flow, five resolved completely.

Transient wall motion abnormality as an indicator of regional myocardial dysfunction was found to be more common following PTCRA compared to PTCA (Williams *et al.* 1996). In spite of the similar cumulative ischaemic time for the patients undergoing both procedures, PTCRA was associated with a lower rate of return to baseline function (p=0.0001) and a longer recovery time (p=0.0001). Patients undergoing PTCRA who went on to develop MI had longer burr times than those who did not develop an MI [mean=4.7 (2.4) versus 3.0 (1.4) minutes; p=0.045].

Using the NACI registry, Waksman *et al.* (1996) reviewed the experience of 3,265 patients and reported that the odds of in-hospital MI (Q-wave and non-Q-wave) was increased in PTCRA compared to transluminal extraction atherectomy (odds ratio [OR]=2.44; 95% CI=1.28, 4.54), excimer lasers (OR=1.72; 95% CI=1.08, 2.78), directional atherectomy (OR=1.05; 95% CI=0.68, 1.61) and Palmaz-Schatz stenting (OR=1.69; 95% CI=0.95, 3.03), and after adjusting for known confounders.

Technical failures

Technical failures arise when there is inability of the device to perform its function due to reasons arising from the characteristics of the lesion, mechanical problems with the device or operator skill or technique. In the context of clinical trials, technical failure often results in subjects crossing over from one treatment arm to another. The experimental nature of the trial may be preserved by retaining original group assignments in the analysis of results (the intention-to-treat principle, see Table 18). However, the threshold above which even this technique is unable to cope with the extent of crossovers is unknown, lending support to the general recommendation that such events be kept to a minimum.

The pooled result of the comparative risk of technical failure from PTCRA compared to PTCA does not suggest any statistically significant differences in the relative or absolute risks (Table 16). There is a lack of evidence addressing the significance and relevance of specific surrogate markers indicating the presence of minimal myocardial injury (e.g. troponin elevation) and its relationship with PTCRA.

Table 16 Incidence of technical failures in trials examining the effectiveness of PTCRA with adjunctive PTCA versus PTCA alone.*

Study	PTCRA-PTCA		PTCA Alone		Relative Risk (95% CI)	Absolute Risk per 100 (95% CI)
	Number with Technical Failure	Total Number of Subjects	Number with Technical Failure	Total Number of Subjects		
Dill *et al.* 2000	13	252	13	250	0.99 (0.47, 2.10)	-0.04 (-3.92, 3.84)
Eltchaninoff *et al.* 1997	0	24	0	26	---	0.00 (-7.48, 7.48)
Reifart *et al.* 1997	7	231	15	222	0.45 (0.19, 1.08)	-3.73 (-7.70, 0.24)
Guerin *et al.* 1996	1	32	1	32	1.00 (0.06, 15.30)	0.00 (-8.52, 8.52)
Danchin *et al.* 1995	10	50	4	50	2.50 (0.84, 7.44)	12.00 (-1.40, 25.40)
Pooled Result	-	-	-	-	0.98 (0.46, 2.10)	-0.57 (-3.90, 2.76)

* Abbreviations: CI=confidence interval; PTCA=percutaneous transluminal coronary angioplasty; PTCRA=percutaneous transluminal coronary rotational atherectomy.

In summary, the available evidence suggests that PTCRA with or without PTCA is no more likely to result in death, Q-wave infarcts or emergency surgery compared to PTCA alone either during the in-hospital period or within six months of the procedure. Patients are also less likely to experience angiographic dissection or proceed to bailout stenting, although minor complications such as temporary vessel spasm and slow flow are increased. PTCRA of in-stent restenosis may have a poorer safety outcome than PTCA. Perforation rates are not statistically significantly different from those associated with PTCA, so it would appear the PTCRA is as safe as PTCA in the first 24 hours of the procedure. However, there is insufficient data to conclude whether PTCRA is as safe as PTCA in revascularising different types of coronary artery lesions.

Is it effective?

Descriptive characteristics of included studies

The literature search uncovered a total of 51 studies providing evidence about the comparative effectiveness of rotational atherectomy. The ideal study design for assessing the clinical effectiveness of a therapeutic procedure is a randomised controlled trial. Sixteen such reports describing the results of 13 studies were identified; two studies were reported twice in the literature. In addition, 36 comparative studies and case series applying designs that were more prone to producing biased estimates of effect were identified.

Sixteen reports of RCTs (NHMRC level II) were identified (Danchin *et al.* 1995, Guerin *et al.* 1996, Jacksch *et al.* 1996, Eltchaninoff *et al.* 1997, Erbel *et al.* 1997, Niazi *et al.* 1997, Reifart *et al.* 1997, Reisman *et al.* 1997, Sharma *et al.* 1999, vom Dahl *et al.* 1999b, Buchbinder *et al.* 2000, Dill *et al.* 2000, Sharma *et al.* 2000, vom Dahl *et al.* 2000, Safian *et al.* 2001, Whitlow *et al.* 2001). The information contained in the article by Erbel *et al.* (1997) was repeated by Dill *et al.* (2000), and Sharma *et al.* (2000) and vom Dahl *et al.* (2000) published updates of results presented in 1999. All subsequent discussions make use of data presented in the latter reports. The study by Danchin *et al.* (1995) was a

randomised crossover trial; only the results prior to the receipt of the second treatment modality were used in this evaluation. Information from five RCTs was available in abstract form only (Niazi *et al.* 1997, Reisman *et al.* 1997, Buchbinder *et al.* 2000, Sharma *et al.* 2000, vom Dahl *et al.* 2000).

Except for the trial by Niazi *et al.* (1997), all RCTs were conducted in one of two European countries (France and Germany) or the United States (Table 17). Of those studies reporting dates of enrollment, patients were recruited in the early to mid-1990s. One study described a recruitment process that was suspended for four months (September to December 1992) due to the "market withdrawal of the Rotablator system" (Reifart *et al.* 1997). No further information was given about the reasons for withdrawal and recruitment proceeded ostensibly after the recall was rescinded. Dill *et al.* (2000) reported an analysis of interim results during the course of the study indicated that, based on statistical advice, enough information had already been accumulated so the study was brought to a close.

Sample sizes were wide-ranging, although all enrolled at least 50 subjects. Overall, the experiences of 3,885 patients were described. Participants had a mean age of between 55 and 65 years and all studies reported a preponderance of male subjects.

Table 17 Descriptive characteristics of randomised controlled trials.*

Study	Location	Dates of Enrolment	Characteristics of the Study Population†			
			Size	Age (years) Mean (SD)	Sex Ratio (M:F)	Follow-up
Safian *et al.* 2001	USA	‡	222	I=67 (10) C=65 (10)	I=72:32 C=83:35	6 months
Whitlow *et al.* 2001	USA	‡	497	I=62.3 (10.6) C=62.4 (11.2)	I=157:92 C=175:73	1 year
Buchbinder *et al.* 2000#	USA	‡	675	I=63.6 C=64.4	I=223:105 C=239:103	In-hospital
Dill *et al.* 2000	Germany	May 1992 to May 1996	502	I=61 (9) C=62 (9)	I=185:67 C=186:64	6 months
vom Dahl *et al.* 2000#	Germany	‡	298	T=61 (11)	T=239:29	6 months
Sharma *et al.* 2000#	USA	‡	200	?	?	In-hospital
Eltchaninoff *et al.* 1997	France	‡	50	I=61 (11) C=56 (11)	I=21:5 C=22:2	In-hospital
Niazi *et al.* 1997#	Saudi Arabia	To Feb 1997	150	?	I=130:20 C=132:18	6 months
Reifart *et al.* 1997§	Germany	Oct 1991 to Aug 1992 Jan 1993 to Dec 1993	685	I=61.6 (10.0) C(a)=62.5 (9.5) C(b)=61.7 (8.8)	I=184:47 C(a)=180:42 C(b)=180:52	6 months to 1 year
Reisman *et al.* 1997#	USA	‡	442	?	I=135:87 C=154:66	?
Guerin *et al.* 1996	France	Apr 1992 to Sep 1993	64	I=64.6 (10.8) C=63.3 (10.4)	I=25:7 C=23:9	6 months
Danchin *et al.* 1995¶	France	Jan 1991 to Dec 1992	100	I=57 (10) C=58 (10)	I=42:8 C=43:7	In-hospital

* Abbreviations: C=comparison group; F=female; I=intervention group; M=male; SD=standard deviation; T=total group.
† Information is given for intervention and comparison groups, where available. In one case (vom Dahl *et al.* 2000), total population figures are given.
‡ Unstated, unclear or unknown.
§ C(a)=percutaneous transluminal coronary angioplasty, C(b)=excimer laser coronary angioplasty.
# Available in abstract form only.
¶ Randomised crossover trial. Primary results prior to crossing of therapies analysed.

Components of the study design relating to the quality of the included studies are presented in Table 18. The process of randomisation was adequately described in four studies (Danchin *et al.* 1995, Guerin *et al.* 1996, Reifart *et al.* 1997, Dill *et al.* 2000), all of which used computer-generated random sequences of numbers. However, only Reifart *et al*. (1997) described the concealment process used. Inadequate randomisation and concealment of allocation were found to be related to a 30 per cent over-estimation in the measures of effect (Schulz *et al.* 1995).

Table 18 Methodological quality of randomised controlled trials.*

Study	Random-isation	Conceal-ment of Allocation	Masking	Participant Inclusion	Losses to Follow-up
Safian *et al.* 2001	Adequate	Adequate	Single	ITT	No losses
Whitlow *et al.* 2001	Unclear	Unclear	Unclear	ITT	15 at 6 mths
Buchbinder *et al.* 2000†	Unclear	Unclear	Unclear	Unclear	Unclear
Dill *et al.* 2000	Adequate	Unclear	Unclear	Unclear	74 at 6 mths
vom Dahl *et al.* 2000†	Unclear	Unclear	Unclear	Unclear	2 at 6 mths
Sharma *et al.* 2000†	Unclear	Unclear	Unclear	Unclear	Unclear
Eltchaninoff *et al.* 1997	Unclear	Unclear	Single	Unclear	No losses
Niazi *et al.* 1997†	Unclear	Unclear	Unclear	Unclear	Unclear
Reifart *et al.* 1997	Adequate	Adequate	Unclear	ITT	12 at 6 mths (mean)
Reisman *et al.* 1997†	Unclear	Unclear	Unclear	Unclear	Unclear
Guerin *et al.* 1996	Adequate	Unclear	Single	Unclear	No losses
Danchin *et al.* 1995‡	Adequate	None	None	ITT	No losses

* Abbreviation: ITT=intention to treat.
† Available in abstract form only.
‡ Personal communication, 2001.

Most of the studies did not provide enough information to determine the strategies used to mask patients or investigators or to determine whether analysis was conducted according to originally assigned groups, although two (Guerin *et al.* 1996, Eltchaninoff *et al*. 1997) mentioned that assessors of angiographic outcomes were unaware of treatment allocation. Another two (Danchin *et al.* 1995, Reifart *et al.* 1997) reported that all analyses were conducted using the "intention-to-treat principle". All studies available in full-text reported minimal or no losses to follow-up.

Patient criteria for enrollment differed among the trials (Table 19). Most specified that a certain degree of occlusion of the target vessel had to be present. Eltchaninoff *et al.* (1997) required a reduction in luminal area of more than 50 per cent, Guerin *et al.* (1996) set the lower limit at 60 per cent, Dill *et al.* (2000) specified a range from 70 to 99 per cent, and Danchin *et al.* (1995) enrolled patients with total (100 per cent) occlusions (a patient group specifically excluded by Guerin *et al.* (1996), Eltchaninoff *et al.* (1997) and Whitlow *et al.* (2001)). Other lesion characteristics that differed among the studies were presence of ostial or bifurcational lesions (included by Dill *et al.* (2000) but excluded by Guerin *et al.* (1996), Eltchaninoff *et al.* (1997) and Reifart *et al.* (1997)) and different angulation and size criteria.

Table 19 Patient criteria in randomised controlled trials.*

Study	Patient Criteria
Safian *et al.* 2001	All patients considered suitable candidates for percutaneous revascularisation of a native coronary vessel using PTCRA and in whom elective stenting was not planned (usually because of vessel diameters <3 mm).
	Exclusions: Recent Q-wave myocardial infarction.
Whitlow *et al.* 2001	All patients undergoing PTCRA by a certified study operator (a physician who has performed ≥100 successful PTCRA procedures and certified by specific laboratories) for angina or a positive functional test. Visually-estimated arterial reference size had to be ≤3.25 mm.
	Exclusions: Total occlusions, lesions >20 mm in length, restenotic lesions with >2 prior treatments, vessels containing thrombus, lesions in vein grafts or arterial conduits, and patients with myocardial infarction with creatine kinase-myocardial band >3 times normal within the last week.
Buchbinder *et al.* 2000†	No specific entry criteria reported.
Dill *et al.* 2000	Patients aged 20-80 years with angiographically-documented coronary artery disease and clinical symptoms of angina or anginal equivalents. The target coronary stenosis was considered haemodynamically significant and eligible for the study if there was a reduction in luminal area of 70-99% and absolute stenosis diameters were <1 mm for a length of at least five mm as visually estimated by the operator. In addition, one secondary criterion had to be fulfilled, such as a heavily calcified, ostial or bifurcation location, or one that was eccentric, diffuse or within an angulated (>45°) segment.
	Exclusions: Unstable angina, myocardial infarction within the previous four weeks, previous coronary angioplasty of the target vessel within the last two months, poor left ventricular function (ejection fraction ≤30%), or any other condition that will limit long-term prognosis.
vom Dahl *et al.* 2000†	Symptomatic, diffuse in-stent restenosis (10-50 mm in length) at least three months after stent implantation.
Sharma *et al.* 2000†	No specific entry criteria reported. Tested effectiveness of PTCRA versus PTCA in diffuse in-stent restenosis.
Eltchaninoff *et al.* 1997	Patients were eligible for the study if they had stable or unstable angina with at least one lesion (>50% stenosis) in a native vessel suitable for angioplasty. Additional inclusion criteria for angioscopy were coronary artery lumen diameter between 2.5 and 3.5mm; location of the target lesion in a straight segment of the artery; location of the lesion at least 20mm away from the coronary ostium; absence of left main coronary artery disease.
	Exclusions: Acute myocardial infarction within 24 hours before the procedure, a restenotic lesion, a total occlusion, or a vein graft lesion.
Niazi *et al.* 1997†	No specific entry criteria reported.
Reifart *et al.* 1997	Patients were included if they had target lesions and vessels suitable for all three techniques. Patients with multivessel coronary disease were also eligible, but the culprit lesion was specified as the target before coronary intervention began.
	Exclusions: Lesion characteristics (stenosis angulation >60°, bend stenosis with an outwardly eccentric lumen, and bifurcational lesions requiring double guide wires) and vessel (extreme proximal vessel tortuosity, saphenous bypass graft or presence of intraluminal thrombus [filling defect], and total occlusion deemed not transferable with guide wires). Patients with acute myocardial infarction and those who had undergone PTCA of any other vessel within the last four months were also excluded.
Reisman *et al.* 1997†	No specific entry criteria reported. Tested effectiveness of rotational atherectomy versus PTCA in vessels <3 mm.
Guerin *et al.* 1996	Patients presenting with a significant stenosis (defined as >60% reduction of the lumen diameter as assessed by quantitative computed angiography) in one or more major coronary vessels, a clinical indication for revascularization, and a left ventricular ejection fraction >40%.
	Exclusions: Myocardial infarction within the last month, restenosis, bypass graft lesions, presence of intraluminal defect, ostial lesions, and total occlusions.
Danchin *et al.* 1995	All patients with a chronic (occlusion duration from 10 days to one year) complete (TIMI grade 0) coronary occlusion, and for whom coronary angioplasty was clinically indicated.
	Exclusions: Occlusions with a side branch arising directly at the occlusion site, located in the immediate vicinity of the left main stem, or with a dense periarterial ipsilateral collateral network.

* Abbreviation: PTCA=percutaneous transluminal coronary angioplasty; PTCRA=percutaneous transluminal coronary rotational atherectomy; TIMI=Thrombolysis in Myocardial Infarction (study).

† Available in abstract form only.

Medication given to subjects prior to the procedures usually consisted of acetylsalicylic acid and heparin (Table 20). More recent studies included nitroglycerin (Eltchaninoff *et al.* 1997, Reifart *et al.* 1997, Dill *et al.* 2000, Safian *et al.* 2001, Whitlow *et al.* 2001) and other adjuncts, although through different routes, dosages or timing.

The procedures used in the performance of PTCRA were varied. Most aimed for a burr-to-artery ratio of about 0.7 (although Guerin *et al.* (1996) used a ratio of 50 to 70 per cent). The most recent studies (Safian *et al.* 2001, Whitlow *et al.* 2001) moved away from determining the efficacy of the technology against other comparators, instead concentrating on the efficacy of different PTCRA techniques.

Two studies (Reifart *et al.* 1997, Dill *et al.* 2000) reported using rotational speeds of at least 160,000 revolutions per minute (rpm), while one (Danchin *et al.* 1995) used a speed of 100-200 rpm. The administration of pharmaceutical agents in saline to flush the equipment and affect distal haemodynamic physiology was reported by Dill *et al.* (2000) and Reifart *et al.* (1997).

All studies applied adjunctive PTCA to those undergoing PTCRA. This meant that a subject underwent angioplasty following the completion of rotational atherectomy. Most studies allowed the operator to decide how to perform adjunctive PTCA to attain an optimal post-procedural results. This dependence on individual operator technique was also used to describe the comparison interventions in all studies.

The study by Reifart *et al.* (1997) also included an extra comparison group that received debulking of the atheromatous plaque using two different xenon chloride excimer laser systems followed by adjunctive PTCA.

Table 20 Therapeutic protocols used in intervention and comparison groups in randomised controlled trials.*

Study	Premedication	Intervention	Comparison
Safian *et al.* 2001	Acetylsalicylic acid 325 mg at least 24 hours before the procedure; intravenous heparin 10,000 U administered on insertion of the vascular sheath and as needed to maintain activated clotting time >300 seconds throughout the procedure; continuous nitroglycerin infusion throughout the procedure.	n=104. PTCRA using a stepped burr approach and rpm surveillance to attain a final burr-to-artery ratio of >0.7. Adjunctive PTCA in all patients using nominal inflation pressures with a balloon-to-artery ratio of about 1.	n=118. PTCRA using a stepped burr approach and rpm surveillance to attain a final burr-to-artery ratio of ≤0.7. Adjunctive PTCA in all patients using nominal inflation pressures with a balloon-to-artery ratio of about 1.
Whitlow *et al.* 2001	Flush solution containing nitroglycerin 4 mg, verapamil 5 mg and heparin 2,000 IU per litre.	n=248. PTCRA using a stepped burr approach with a maximum burr-to-artery ratio of >0.70 with or without adjunctive PTCA with maximum balloon inflation pressure ≤1 atm with a 0.25 mm visually oversized balloon.	n=249. PTCRA using a stepped burr approach with a maximum burr-to-artery ratio of ≤0.70 with adjunctive PTCA with a 0.25 mm visually oversized balloon at ≥4 atm.
Buchbinder *et al.* 2000†	Not stated.	n=328. PTCRA and stent placement.	n=342. PTCA and stent placement.
Dill *et al.* 2000	Acetylsalicylic acid; two hours before the procedure, nitroglycerin 2-4 mg/h and nifedipine 0.5-1.5 mg/h with 500 ml saline; intravenous heparin 15,000-20,000 IU bolus to maintain clotting time above 350 seconds during the procedure; use of intracoronary nitroglycerin was left to the operator.	n=252. PTCRA with burr sizes from 1.25-2.5 mm at 160,000-190,000 rpm with each sequence being less than 30 seconds. Intracoronary nitroglycerin 100-200 μg administered after each sequence. Target burr-to-artery ratio was 0.7. Adjunctive PCTA left to the operator.	n=250. PTCA using "approved systems" (balloon length 20-40 mm). Specific technique was left to the operator.
vom Dahl *et al.* 2000†	Acetylsalicylic acid, heparin, ticlopidine.	n=152. PTCRA using a stepped-burr approach with adjunctive low pressure (4-6 atm) PTCA.	n=146. PTCA with the same sized or slightly oversized balloon as that used for stent implantation.
Sharma *et al.* 2000†	Not stated.	n=50. PTCRA.	n=50. PTCA.
Eltchaninoff *et al.* 1997	Acetylsalicylic acid; intravenous heparin 10,000 IU bolus and 150 μg intracoronary nitroglycerin.	n=24. PTCRA using 8F-9F sheath placed in femoral artery. One burr used per lesion with size chosen to obtain a burr-to-artery ratio of 0.7. Adjunctive PTCA performed after PTCRA. Inflation pressures used were <6 atm.	n=26. PTCA using "standard techniques". 8F placed in femoral artery and balloon size chosen to obtain a balloon-to-artery ratio of approximately 1.
Niazi *et al.* 1997†	Not stated.	n=75. PTCRA with adjunctive PTCA and stent placement.	n=75. PTCA with stent placement.

Table 20 (continued) Therapeutic protocols used in intervention and comparison groups in randomised controlled trials.*

Study	Premedication	Intervention	Comparison
Reifart *et al.* 1997	One day prior to procedure, >160 mg acetylsalicylic acid and oral nitrates. Heparin 25,000 IU bolus restricted to patients with long, spiral dissections.	n=231. PTCRA used burr sizes from 1.25-2.25 mm rotating at 160,000-180,000 rpm with each sequence lasting from 10-15 seconds with extended pauses to allow for washout of debris. Teflon sheath over the drive shaft flushed with solution containing a cocktail of heparin 10,000IU, nitroglycerin 2mg, and verapamil 5mg in 500mL saline. Target burr-to-artery ratio was 0.67. Adjunctive PTCA used to obtain <50% residual stenosis. Inflation pressures used were ≤4 atm.	n=232. ELCA used two different 308 nm xenon chloride excimer lasers. The first system used a pulse duration of 210ns, a pulse repetition rate of 20-30Hz, and energy to 45-70mJ/mm^3. The second used a pulse duration of 135 nanoseconds, a pulse repetition rate of 25 Hz, and energy of 45-60 mJ/mm^3. No saline infusion protocol used. Adjunctive PTCA used to obtain <50% residual stenosis. Inflation pressures: ≤4 atm. n=222. PTCA used any approved rapid exchange balloon dilatation system of length 20, 30, 35, and 40 mm. Specific protocols used to achieve optimal angiographic results left to the operator. Recommendations include a balloon-to-artery ratio of 1 and incremental increase of pressure by 1 atm per 10-15 seconds until full expansion.
Reisman *et al.* 1997†	Not stated.	n=222. PTCRA with or without adjunctive PTCA	n=220. PTCA.
Guerin *et al.* 1996	Three days before the procedure, acetylsalicylic acid 250 mg daily. Intravenous heparin 10,000 IU at beginning of procedure.	n=32. PTCRA used a 7F or 8F guide catheter. A single burr (with burr-to-artery ratio of 50-70%) was passed several times over the lesion. Each pass lasted <15 seconds. Adjunctive PTCA used with balloon-to-artery ratio of 1.	n=32. PTCA performed with “standard techniques”.
Danchin *et al.* 1995	Intravenous heparin 10,000 U and acetylsalicylic acid 250-500 mg upon insertion of catheter.	n=50. PTCRA used a 1.3 mm burr rotated at a speed of 100-200 rpm and brought to occlusion. Adjunctive PTCA performed.	n=50. PTCA performed according to preferences of operators.

* Abbreviations: atm=atmosphere; ELCA=excimer laser coronary angioplasty; F=French; IU=International Unit; n=sample size; PTCRA=percutaneous transluminal coronary rotational atherectomy; PTCA=percutaneous transluminal coronary angioplasty; rpm=revolutions per minute.

† Available in abstract form only.

Effectiveness in non-complex coronary artery lesions

There is a general lack of available evidence examining the effectiveness of PTCRA on non-complex lesions of the coronary arteries due largely to operator preference for lesions with more complex morphological characteristics (Zaacks *et al.* 1998). Of the

RCTs retrieved, three enrolled patients with complex lesions (Danchin *et al.* 1995, Guerin *et al.* 1996, Dill *et al.* 2000). Two RCTs that compared PTCRA against another comparator (Eltchaninoff *et al.* 1997, Reifart *et al.* 1997) provided no detailed information to determine the effectiveness of the technology in non-complex lesions because no data were presented nor analyses performed according to lesion type.

The RCT by Reisman *et al.* (1997) is widely cited as providing evidence of the lack of effectiveness of PTCRA in non-complex lesions of the coronary arteries. However, the numbers of patients with Type B_2 and C lesions in the two groups studied were severely disproportionate . Only about half of patients in the group receiving PTCRA had lesions of these types compared to about 80 per cent in the comparison group. Mean post-procedure residual stenosis was 30 per cent (11 per cent) in the group receiving PTCRA with adjunctive PTCA compared to 31 per cent (12 per cent) in those receiving PTCA alone. Procedural success was 99 per cent and 100 per cent, respectively. No long-term results were presented.

MacIsaac *et al.* (1995) reviewed data from a multicentre registry of PTCRA procedures conducted on single lesions. In non-calcified lesions, 1,031 of 1,083 (95.2 per cent) procedures resulted in a successful outcome (compared to 94.3 per cent of 1,078 calcified lesions; $p=0.32$).

Two small case series (Level IV) have been presented. Jones *et al.* (1993) reviewed the experience of 60 patients with lesions of the left main coronary artery. Procedural success was attained in 95 per cent of patients, but a restenosis rate of 50 per cent was observed at follow-up (duration unknown).

Chatelain *et al.* (1992) described the use of PTCRA in 12 patients. Success was seen in five (42 per cent) with another five crossing over to another device. In contrast, Pavlides *et al.* (1992) reported that all 17 patients undergoing PTCRA with adjunctive therapy had a "successful" outcome (although there were no substantial differences between atherectomy and TEC).

In a comparative study (Level III-2), Safian *et al.* (1993) suggested that residual stenoses in coronary arteries following PTCRA was due mainly to the use of undersized devices. The computed efficiency of PTCRA (defined as the ratio of the residual lumen diameter to the device diameter) was 92 per cent compared to 71 per cent following PTCA alone ($p<0.001$).

Effectiveness in complex coronary artery lesions

Data from five RCTs were extracted to provide information about the effectiveness of PTCRA in the management of complex lesions. Two studies (Guerin *et al.* 1996, Dill *et al.* 2000) restricted enrollment to patients with complex lesions. While using entry criteria that allowed the inclusion of patients with non-complex (Type A) lesions, two studies (Eltchaninoff *et al.* 1997, Reifart *et al.* 1997) are included in this discussion because neither reported separate results according to lesion type. Moreover, the proportion of subjects with such lesions was small. In the study by Eltchaninoff *et al.* (1997), five out of 50 subjects (10 per cent) had Type A lesions while Reifart *et al.* (1997) reported that 21 of 685 participants (3 per cent) had non-complex lesions. If lesion type is associated with specific outcomes according to treatment received, the magnitude or direction of

systematic deviation of effect estimates cannot be measured without additional information, although small proportions may attenuate this potential bias.

The baseline clinical characteristics of a total of 1,066 patients with complex coronary artery lesions undergoing PTCRA with adjunctive PTCA (PTCRA-PTCA) or PTCA alone are shown in Table 21. Participants in the PTCRA-PTCA group had a mean age of 61.7 (9.7) years, although the group enrolled by Eltchaninoff *et al.* (1997) was statistically significantly younger than the other groups. About 20 per cent of the total PTCRA-PTCA group reported suffering from unstable angina, although the proportion of such subjects from the trial by Guerin *et al.* (1996) was about twice the pooled result. There were no differences in the distributions of males, pre-existing diabetes, previous MI and previous CABG surgery.

The group receiving PTCA alone did not show statistically significant differences in the distributions of age, sex, pre-existing diabetes or previous CABG surgery. The pooled proportion of participants who reported unstable angina was slightly higher, but the group enrolled by Reifart *et al.* (1997) had a smaller proportion compared to that of Guerin *et al.* (1996) and Eltchaninoff *et al.* (1997). A similar result (but in the opposite direction) was seen for subjects reporting previous MI.

In comparing the two treatment groups overall, only the lower mean age in the PTCRA-PTCA group enrolled by Eltchaninoff *et al.* (1997) was found to be statistically significantly different. All other clinical characteristics were similarly distributed between the groups.

Angiographic baseline characteristics were relatively more heterogeneous than clinical characteristics. Overall, lesions were more commonly located in the left anterior descending artery (in about 45 per cent of cases), followed by the right coronary artery (about 25 per cent of cases) and the left circumflex artery (in about 20 per cent of cases). Only three studies (Eltchaninoff *et al.* 1997, Reifart *et al.* 1997, Reisman *et al.* 1997) reported details about the type of lesion according to ACC/AHA criteria.

The morphology of vascular lesions was described in three studies (Guerin *et al.* 1996, Reifart *et al.* 1997, Dill *et al.* 2000), although the definitions used to determine whether lesions met certain criteria were not. For the most part, the studies by Dill *et al.* (2000) and Reifart *et al.* (1997) enrolled participants with similar morphological features: about two in five had calcified lesions; four in five, eccentric lesions; three in five, lesions of less than 10mm; and about 15 per cent were angulated beyond 45 degrees. The subjects enrolled by Guerin *et al.* (1996) showed different characteristics. Statistically significant differences in the diameter, length and per cent stenosis of the arteries were also apparent.

Table 21 Baseline clinical and angiographic characteristics of subjects enrolled in four trials examining the effectiveness of PTCRA with adjunctive PTCA versus PTCA alone.*

Characteristic	PTCRA-PTCA					PTCA Alone				
	Dill *et al* 2000	Eltchaninoff *et al* 1997	Reifart *et al* '97	Reisman *et al* 1997	Guerin *et al.* 1996	Dill *et al* 2000	Eltchaninoff *et al.* 1997	Reifart *et al.* '97	Reisman *et al.* '97	Guerin *et al.* 1996
Subjects, n	252	24	231	222	32	250	26	222	220	32
Age, years, mean (SD)	61 (9)	56 (11)	61.6 (10)	†	64.6 (10.8)	62 (9)	61 (11)	62.5 (9.5)	†	63.3 (10.4)
Males, n (%)	185 (73.4)	22 (91.7)	184 (79.6)	135 (61)	25 (78.1)	186 (74.4)	21 (80.8)	180 (81.1)	174 (70)	23 (71.9)
Diabetes, n (%)	46 (18.2)	3 (12.5)	35 (15.2)	†	†	48 (19.2)	3 (11.5)	36 (16.2)	†	†
Unstable Angina, n (%)	x‡	6 (25)	42 (18.2)	†	13 (40.6)	x	9 (34.6)	27 (12.2)	†	15 (46.9)
Previous MI, n (%)§	109 (43.2)	10 (41.7)	109 (47.2)	†	10 (31.2)	104 (41.6)	6 (23.1)	99 (44.6)	†	7 (21.9)
Previous CABG, n (%)	20 (7.9)	†	13 (5.6)	†	2 (6.2)	20 (8)	†	13 (5.8)	†	3 (9.4)
Location of Lesion, n (%)	249 (100)	24 (100)	227 (100)		32 (100)	248 (100)	26 (100)	219 (100)		32 (100)
LAD	145 (58.2)	10 (41.7)	117 (51.7)		19 (59.4)	127 (51.2)	12 (46.2)	106 (48.4)		15 (46.9)
LCx	49 (19.7)	3 (12.5)	45 (19.8)	†	8 (25)	50 (20.2)	8 (30.8)	54 (24.6)	†	8 (25)
RCA	55 (22.1)	11 (45.8)	65 (28.6)		5 (15.6)	71 (28.6)	6 (23.1)	59 (26.9)		9 (28.1)
TIMI Flow < 3, n (%)	121 (52.4)	†	51 (22.1)	†	†	117 (50.6)	†	47 (21.1)	†	†
Lesion Type, n (%)#		24 (100)	231 (100)	222 (100)			26 (100)	222 (100)	220 (100)	
A		2 (8.3)	3 (1.3)	98 (44)			3 (11.5)	11 (5.0)	46 (21)	
B_1	†	7 (29.2)	47 (20.3)		†	†	11 (42.3)	50 (22.5)		†
B_2		10 (41.7)	149 (64.5)	124 (56)			9 (34.6)	139 (62.6)	174 (79)	
C		5 (20.8)	32 (13.8)				3 (11.5)	22 (9.9)		
Lesion Morphology, n (%)										
Calcified	98 (42)		88 (38.1)		23 (71.9)	74 (31)		82 (36.9)		19 (59.4)
Eccentric	180 (78)	†	185 (80.1)	†	18 (56.2)	193 (82)	†	168 (75.7)	†	22 (68.8)
Lesion Length < 10 mm	128 (56)		131 (57.7)		†	137 (60)		124 (55.8)		†
Angulation ≥ 45°	25 (11)		36 (15.6)¶		12 (37.5)**	27 (12)		30 (13.5)¶		11 (34.4)**
Bifurcation	117 (51)		37 (16)		†	115 (49)		41 (18.5)		†
Reference Diameter, mm, mean (SD)	2.6 (0.4)	3.0 (0.5)	2.93 (0.57)	2.45 (0.40)	2.75 (0.33)	2.8 (0.5)	3.2 (0.6)	2.93 (0.62)	2.43 (0.39)	2.86 (0.39)
Length, mm, mean (SD)	13.3 (10.2)	†	11.4 (7.7)	†	9.1 (4.4)	12.4 (9.2)	†	10.6 (7.5)	†	9.0 (4.3)
Minimal Lumen Diameter, mm, mean (SD)	0.65 (0.27)	1.1 (0.2)	0.71 (0.32)	1.73 (0.34)	†	0.68 (0.31)	1.1 (0.5)	0.74 (0.33)	1.75 (0.47)	†
Stenosis, %, mean (SD)	75 (8.7)	63 (8)	76 (12)	†	†	76 (9.2)	67 (11)	75 (11)	†	†

***** Abbreviations: CABG=coronary artery bypass graft; LAD=left anterior descending artery; LCx=left circumflex artery; MI=myocardial infarction; PTCA=percutaneous transluminal coronary angioplasty; PTCRA=percutaneous transluminal coronary rotational atherectomy; RCA=right coronary artery; SD=standard deviation; TIMI=Thrombolysis in Myocardial Infarction (study).

† Unknown or unstated. ‡ Excluded. # ACC/AHA Classification (Table 2). ¶ Angulation between 45° to 60°. ****** Degree of angulation unspecified.

§ Events occurring within a specific time period prior to the treatment were excluded (Table 19). Eltchaninoff *et al*. (1997), within 24 hours; Dill *et al*. (2000) and Guerin *et al*. (1996), within one month; Reifart *et al*. (1997), within four months.

Evidence exists that each of the five RCTs enrolled groups had clinically and angiographically dissimilar characteristics (at least within statistically relevant bounds). The interpretation of effect size summaries, therefore, must take into account the presence of potentially sizeable systematic deviations compared to similar effect sizes derived from studies without such dissimilar groups. To some extent, the use of random effects models to obtain summary effect size estimates will generally produce more conservative results, but this is not always the case (Poole & Greenland 1999) and it is prudent to moderate inferences drawn from such methods with the knowledge that the potential for bias is present.

Three studies reported restenosis rates at follow-up (Guerin *et al.* 1996, Reifart *et al.* 1997, Dill *et al.* 2000). The outcome was defined similarly across all three studies: ≥ 50 per cent stenosis determined angiographically at follow-up. Both Guerin *et al.* (1996) and Dill *et al.* (2000) provided data at six months of follow-up while Reifart *et al.* (1997) presented information up to one year. If the assumption is made that risks remain stable throughout the follow-up period and that restenosis occurs evenly throughout the observation time, useful information may be extracted (Table 22).

Table 22 Incidence of restenosis at six months of follow-up in trials examining the effectiveness of PTCRA with adjunctive PTCA versus PTCA alone.*

Study	PTCRA-PTCA		PTCA Alone		Relative Risk (95% CI)	Absolute Risk per 100 (95% CI)
	Number with Restenosis	Total Number of Subjects	Number with Restenosis	Total Number of Subjects		
Dill *et al.* 2000	80	163	87	170	0.96 (0.77, 1.19)	-2.10 (-12.84, 8.64)
Reifart *et al.* 1997†	42	145	26	109	1.21 (0.80, 1.85)	5.11 (-5.77, 16.00)
Guerin *et al.* 1996	11	28	11	26	0.93 (0.49, 1.77)	-3.02 (-6.23, 8.45)

* Abbreviations: PTCA=percutaneous transluminal coronary angioplasty; PTCRA=percutaneous transluminal coronary rotational atherectomy.

† Results are for follow-up six months interpolated from one year data.

Overall, there were no statistically significant differences in the restenosis rates in the group receiving PTCRA with adjunctive PTCA compared to the group receiving PTCA alone (RR=1.00; 95% CI=0.83, 1.20; p=0.998; Figure 9) with no substantial statistical heterogeneity apparent (Q=1.04; df=2; p=0.594). The pooled risk difference also was statistically non-significant (RD=0.01; 95% CI=-0.06, 0.08; p=0.767). The results of one trial were not included due to the lack of primary data (Niazi *et al.* 1997).

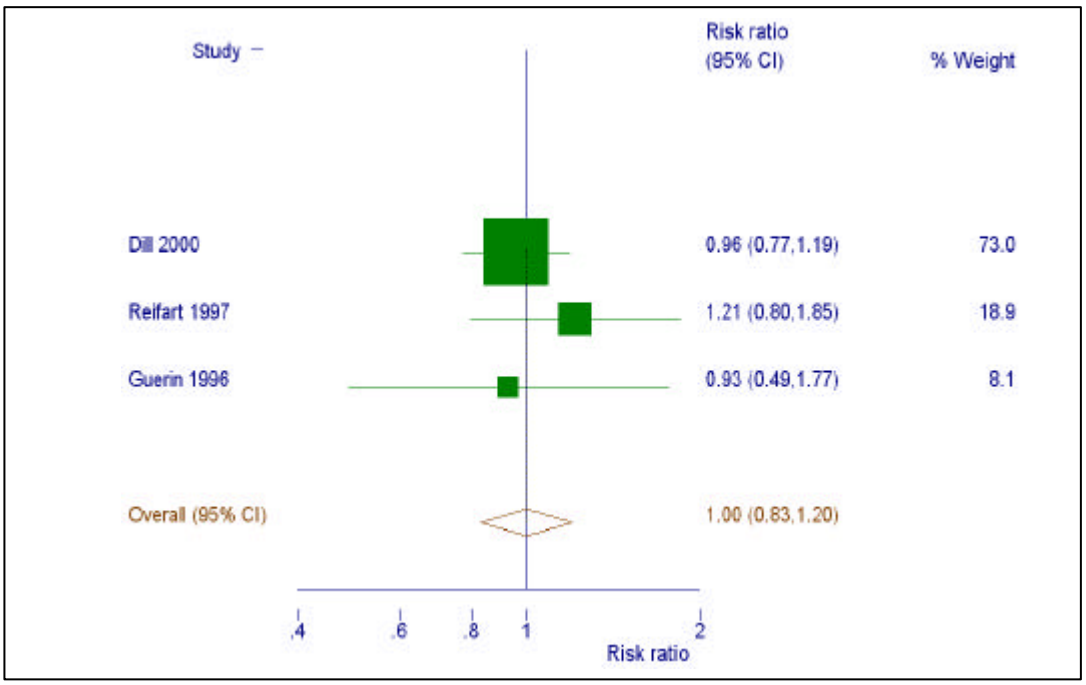

Figure 9 **Risk of restenosis at six months in patients receiving PTCRA with adjunctive PTCA versus PTCA alone.**

Particular morphological characteristics that distinguish specific complex lesions were examined by several authors. The results of these studies are described below and summarized in Table 23.

Chronic total occlusions

The study by Danchin *et al.* (1995) was the only RCT that examined the effectiveness of PTCRA with adjunctive PTCA versus PTCA alone in patients with chronic total occlusions. The study collected data for in-hospital outcomes alone and provides no information on the main outcome of interest, six-month restenosis rates.

Primary or procedural success, defined as recanalisation of the occluded vessel with ≤50 per cent residual stenosis on quantitative coronary angiography with no MACE, was achieved in 33 of 50 patients receiving PTCRA-PTCA and in 30 of 50 patients receiving PTCA alone. This result shows no statistically significant difference between the groups (RR=1.10; 95% CI=0.81, 1.49; RD=0.06; 95% CI=-0.12, 0.25; p=0.534).

In a case series (NHMRC level IV) that enrolled 200 patients, Kini *et al.* (2000) suggested that procedural success can be attained in 99.5 per cent of cases in which the lesion was crossed by the guide wire. Mean post-procedure residual stenosis was estimated as 12 per cent (10 per cent). After a follow up of 11 (4) months, the target vessel revascularisation rate was 20 per cent.

Similar results were seen in another case series (NHMRC level IV) reported by Omoigui *et al.* (1995). Success without major complications occurred in 91 per cent of all occlusions (135 of 145) with a final residual stenosis of 26.9 per cent (16.8 per cent) after adjunctive PTCA. Length of follow-up was unstated, but angiographic results indicated that restenosis was evident in 62.5 per cent of lesions.

Braden *et al.* (1999) reported on the long-term follow-up [mean=46.2 (6) months] of 122 consecutive patients. Restenosis was present in 20 per cent.

Calcified lesions

Calcified coronary artery lesions are difficult to treat and represent both a therapeutic and an operator challenge. Because of their morphology and, often, anatomical placement within coronary arteries (e.g. at ostial sites), revascularisation procedures involving these lesions must be carefully managed for several reasons:

- it may be difficult to pass a guidewire across such lesions and deploy an interventional catheter;
- assuming a guidewire can be passed, PTCA (with or without stenting) is often unsuccessful because lesion architecture does not allow sufficient balloon expansion to permit a sustained increase in lumen diameter;
- if balloon expansion is possible with standard PTCA (with or without stenting), uneven deployment, as a result of anatomy and architecture, may result in:
  i) parts of the lesions breaking off and embolising downstream; and/or
  ii) exposing underlying atheromatous material to the blood stream resulting in thrombosis.

It is unlikely that high-level evidence will be collected to examine the effectiveness of PTCRA on calcified lesions given that it might not be feasible to construct a clinical trial that compares PTCRA of these lesions with an appropriate comparator. PTCA is not appropriate (as per above), while CABG surgery may be appropriate. However, it may be unlikely that CABG surgery will be undertaken for single vessel disease, particularly if a patient has significant underlying comorbidities that are, of themselves, contraindicated for CABG surgery (e.g. advanced age, severe respiratory or cardiac disease, renal failure, dialysis, diabetes).

Hoffmann *et al.* (1998) described a retrospective study with case matching (NHMRC level III-2) that compared the effectiveness of PTCRA (Group 1; n=147) versus either Palmaz-Schatz stent implantation (Group 2; n=103) or PTCRA with adjunctive stent implantation (Group 3; n=56) in patients with moderate to severe calcification of native coronary arteries. All patients received adjunctive PTCA. Patient characteristics were similar among the groups. However, lesion characteristics evinced systematic group differences. Lesions treated with PTCRA alone (Group 1) were more likely to be shorter, eccentric, ostial or used in smaller vessels while Group 3 lesions were more likely to be bifurcational.

PTCRA with adjunctive stent implantation showed a highly statistically significantly smaller final per cent diameter stenosis [mean=4.2 per cent (SD=15.3 per cent)] compared with PTCRA alone [14.1 per cent (13.3 per cent)] or stent implantation alone [26.7 per cent (16.9 per cent)]. The same result was seen for the acute gain in luminal

diameter. The procedural success rates were similar in the three groups (98.6 per cent, 98.0 per cent and 98.2 per cent for Groups 1, 2, and 3, respectively). After nine months of follow-up, the rates of target lesion revascularisation were lowest in Group 3 (18 per cent) compared to Groups 1 and 2 (22 per cent and 18 per cent, respectively), although these results failed to reach statistical significance (p=0.152).

The lack of association between procedural success rates and the degree of calcification in coronary lesions was examined by Altmann *et al.* (1993) in a comparative study (NHMRC level III-2). After stratifying 675 lesions into three categories of calcifications [none or mild (27 per cent), moderate (56 per cent) or dense (17 per cent)], the authors found comparable procedural success rates across the groups (96 per cent, 96 per cent and 92 per cent, respectively).

Ostial lesions

In a retrospective review of case records (NHMRC level III-2), Koller *et al.* (1994) compared the effectiveness of PTCRA (n=29) with transluminal extraction catheter (TEC, n=72) in patients with coronary ostial stenoses in which the degree of narrowing was at least 50 per cent. Except in a single case, all patients with lesions affecting saphenous vein grafts underwent TEC rather than PTCRA due to the risk of distal embolisation. The cutter and burr sizes used were routinely under-sized by 0.5 to 1.0mm compared to the reference segments and adjunctive PTCA was left to the discretion of the physician. All patients received acetyl salicylic acid, heparin, dextran and nitroglycerin before the procedure.

No significant differences were apparent with regard to minimal lumen diameter (MLD) or per cent stenosis at baseline. Procedural success following PTCRA was 69 per cent compared to the TEC rate of 52 per cent (p=0.119). Following adjunctive PTCA, both showed a procedural success rate of about 90 per cent. After a mean follow-up of five months, about 40 per cent of all vessels treated with PTCRA showed evidence of angiographic stenosis.

Two case series (NHMRC level IV) were reported in the literature. Sixty three patients with ostial lesions treated with PTCRA showed an overall success rate of 92 per cent (Zimarino *et al.* 1994). About the same percentage of aorto-ostial (lesions involving the junction between the aorta and the orifice of the RCA, LAD or saphenous vein graft) and branch-ostial (involving the junction between a large epicardial vessel and the orifice of a major branch) lesions were treated successfully using PTCRA.

In 106 patients with a single ostial stenosis of the RCA, 99 (93 per cent) achieved procedural success (Bernardi *et al.* 1993). Mean post-PTCRA residual stenosis was 38 per cent; following adjunctive PTCA, residual stenosis was 18 per cent. A restenosis rate of 51 per cent was reported at six months of follow-up.

Angulated lesions

Chevalier *et al.* (1994) observed 111 patients with 123 angulated stenoses of greater than 45 degrees. The authors report a success rate of 86 per cent with dissection occurring in one-third of attempts. Residual stenosis was 47 per cent following PTCRA and 24 per cent following adjunctive PTCA.

Long lesions

The association between lesion length and outcome following PTCRA was examined by Reisman *et al.* (1993). A registry was searched to accumulate 1,276 lesions treated with PTCRA. The lesions were grouped according to length. Group 1 (n=953; 74.7 per cent) lesions were between 1 and 10mm, Group 2 (n=180; 14.1 per cent) lesions between 11 and 15mm, and Group 3 (n=143; 11.1 per cent) lesions between 15 and 25mm. Procedural success following PTCRA was 86 per cent, 84 per cent and 83 per cent in Groups 1, 2, and 3, respectively. Following adjunctive PTCA, success rates increased to 95 per cent, 97 per cent and 92 per cent, respectively.

Table 23 Procedural success and restenosis rates in comparative studies examining the efficacy of PTCRA with or without adjunctive PTCA in complex lesions of the coronary arteries.*

Characteristic Lesion Complexity and Study	Number of Subjects Undergoing PTCRA	Main Entry Criteria	Procedural Success Rate (%)	Restenosis Rate (%)	Length of Follow-Up mths (SD)
Chronic total occlusions					
Danchin *et al.* 1995	50	See Table 19	66	---	---
Kini *et al.* 2000†	200	Chronic total occlusions crossed by the guide wire	99.5	?‡	11 (4)
Braden *et al.* 1999†	122	Chronic total occlusions crossed by the guide wire	?	20	46.2 (6)
Omoigui *et al.* 1995†	139	Chronic total occlusions crossed by the guide wire	91.0	62.5	?
Calcified lesions					
Hoffmann *et al.* 1998	147	Lesion of a native coronary artery with moderate to severe calcification	98.6	?	9
Altmann *et al.* 1993†	675	Extent of calcification	95	?	12
Ostial lesions					
Koller *et al.* 1994	29	Ostial stenosis of ≥50% located within 3 mm of the vessel orifice	69	39	5.4 (1.6)
Zimarino *et al.* 1994	63	Aorto-ostial or branch-ostial lesions	93	---	---
Bernardi *et al.* 1993†	106	Single ostial stenosis of the RCA	93	51	6
Angulated lesions					
Chevalier *et al.* 1994†	111	Diastolic angulation >45°	86	---	---
Long lesions					
Reisman *et al.* 1993†	1,276	Lesions of various lengths	84	---	---

* Abbreviations: PTCA=percutaneous transluminal coronary angioplasty; PTCRA=percutaneous transluminal coronary rotational atherectomy.
SD Standard deviation
† Available in abstract form only.
‡ Unknown or unstated.

Effectiveness in treating in-stent restenosis

The ROSTER Trial (Sharma *et al.* 1999) reported the results of PTCRA versus PTCA in the treatment of diffuse in-stent restenosis. The trial enrolled a total of 200 patients assigned in equal numbers to the two procedures. Preliminary results show that mean pre- and post-procedural MLDs and the gain in luminal diameter following the

placement of the stent were comparable between the groups (Table 24). Prior to the treatment for in-stent restenosis, the mean MLD between the groups was similar. Rotational atherectomy produced a larger mean MLD compared to PTCA.

Table 24 Results of the ROSTER trial (Sharma *et al.* 1999).

Quantitative Analysis (mm)	PTCRA (n=50)	PTCA (n=50)	*p* value
Initial stent placement, mean (SD)			
Pre-procedure MLD	0.86 (0.16)	0.89 (0.18)	0.381
Post-procedure MLD	3.06 (0.31)	3.01 (0.28)	0.399
Acute luminal gain	2.42 (0.21)	2.36 (0.19)	0.137
During treatment for in-stent restenosis, mean (SD)			
Pre-procedure MLD	0.84 (0.21)	0.91 (0.32)	0.581
Post-procedure MLD	2.88 (0.26)	2.61 (0.31)	<0.001
Acute luminal gain	2.08 (0.21)	1.72 (0.21)	<0.001

* Abbreviations: MLD=minimum lumen diameter; PTCA=percutaneous transluminal coronary angioplasty; PTCRA=percutaneous transluminal coronary rotational atherectomy; SD=standard deviation.

The trial also reported 12 month follow-up results indicating the rates of clinical restenosis following PTCRA were statistically significantly reduced (Sharma *et al.* 2000). Clinical restenosis was reported in 32 per cent of patients receiving PTCRA compared to 45 per cent receiving PTCA ($p<0.05$). The authors do not provide enough information to calculate 95% confidence intervals.

The results of the ROSTER trial contrast with those from the ARTIST trial (vom Dahl *et al.* 2000). The latter study enrolled 298 patients with symptomatic, diffuse in-stent restenosis. Participants were assigned to PTCRA with low-pressure PTCA (n=152) or PTCA alone (n=146). Post-procedural angiographic success (defined as residual stenosis of less than 30 per cent) was 89 per cent for PTCRA and 88 per cent for PTCA. Minimum lumen diameter and luminal gain were likewise similar between the groups (no data given).

After six months of follow-up, those receiving PTCA alone were noted to have more favourable outcomes in terms of event-free survival (91.1 per cent versus 79.6 per cent; $p=0.005$), MLD [1.2 mm (0.6) versus 1.0 mm (0.6); $p=0.008$], residual stenosis [56 per cent (20) versus 64 per cent (22); $p=0.005$], restenosis rate (51.2 per cent versus 64.8 per cent; $p=0.04$), and rates of target lesion revascularisation (36.2 per cent versus 47.8 per cent; $p=0.06$).

The results of these RCTs should be considered with care given that important information (e.g. the patient population, quality domains, etc.) was not available in the abstract. Moreover, the distributions of potential confounding factors are not given. Although the common expectation is that measured and unmeasured characteristics will be equally distributed between the groups, no information is presented to support this position. Procedural characteristics also differ between the two.

Four comparative studies (NHMRC level III-2) have been published comparing PTCRA and adjunctive PTCA with PTCA alone in the treatment of in-stent restenosis (Lee *et al.* 1998, Fukuda *et al.* 1999, Lauer *et al.* 2000, Schiele *et al.* 2000). The first two studies suggest the presence of relative gains in the long-term while the last two do not. Fukuda *et al.* (1999) compared the experience of 44 patients with diffuse (>75 per cent of the length of the stent) in-stent restenosis (PCTRA-PTCA: n=23; PTCA: n=21). The groups

were similar in terms of clinical and baseline angiographic characteristics (although more people in the PTCRA-PTCA group had previously undergone haemodialysis and had a greater number of previous PTCA attempts). At baseline, mean MLD for the lesion was 0.61mm (0.13) in the PTCRA-PTCA group and 0.59mm (0.18) in the PTCA group.

The authors reported that procedural success was attained in all patients in both groups. The mean post-procedure MLD did not differ between the groups in any significant fashion [PTCRA-PTCA=2.72mm (0.19) versus PTCA=2.78mm (0.25); $p=0.373$]. After a mean follow-up of about three months, restenosis of at least 50 per cent was present in 33.3 per cent of those who underwent PTCRA-PTCA versus 71.4 per cent in those receiving PTCA alone ($p=0.013$). The proportion of diffuse restenotic cases on follow-up were similarly different (28.6 per cent in the PTCRA-PTCA group versus 80.0 per cent in the PTCA group; $p=0.020$).

The second study (Lee *et al.* 1998) enrolled 81 patients (PCTRA-PTCA: n=36; PTCA: n=45). Baseline clinical characteristics were comparable between the groups (although the PTCRA-PTCA group was more likely to have multivessel disease) as were the characteristics of the original lesions (although the PTCRA-PTCA group was more likely to have a long stent implanted). The complete revascularisation rates for both groups were similar (89 per cent for PTCRA-PTCA compared to 87 per cent for PTCA; $p=0.784$) with procedural success being 100 per cent in both groups. Following the repeat intervention, there were no differences in the mean MLD [PTCRA-PTCA=2.62mm (0.56); PTCA=2.57mm (0.55); $p=0.688$) or acute luminal gain (PTCRA-PTCA=2.16 mm (0.52); PTCA=1.94mm (0.63); $p=0.096$). Clinical recurrence at six months was significantly lower in the PTCRA-PTCA group (25 per cent versus 47 per cent; $p=0.042$).

The mean MLD of 190 lesions treated with PTCRA-PTCA was 2.71mm (0.53) in the study by Lauer *et al.* (2000). This was statistically significantly different from 301 lesions treated with PTCA alone [2.51mm (0.64); $p<0.001$]. These gains did not continue at the six-month follow-up period [PTCRA-PTCA=1.62mm (0.89); PTCA=1.53mm (0.87); $p=0.320$].

The study by Schiele *et al.* (2000) enrolled 70 patients (PTCRA-PTCA: n=30; PTCA: n=40) who had angiographic and intravascular ultrasonographic data before and after the repeat procedure of in-stent restenosis. Patients who received PTCRA-PTCA had smaller mean MLDs [0.73mm (0.28) versus 0.98mm (0.31); $p=0.002$], larger per cent diameter stenosis [71 per cent (11) versus 63 per cent (13); $p=0.01$], longer lesions [12.7mm (7.4) versus 8.0mm (3.7); $p=0.001$], smaller luminal cross-sectional area [1.6mm^2 (0.7) versus 2.0mm^2 (0.9); $p=0.03$], and a larger neointimal tissue cross-sectional area [5.9mm^2 (1.7) versus 4.9mm^2 (2.1); $p=0.02$).

Following the procedure, the patients who received PTCRA-PTCA had a larger immediate gain resulting in significant differences between the groups in post-procedural angiographic and ultrasonographic parameters. Clinical follow-up after one year did not differ between the groups.

Similar null findings are suggested by the a retrospective review of cases (NHMRC level III-2) published by Jolly *et al.* (1999) comparing 116 patients undergoing PTCA with 30 patients receiving PTCRA for in-stent restenosis. Patients were similar in terms of lesion length, MLD and baseline per cent stenosis. Post-procedure success rates were similarly favorable (100 per cent for PTCRA compared to 96 per cent for PTCA; $p=0.266$). After

a median follow-up time of eight months, there were no significant differences in the rates of target vessel revascularisation (16 per cent in PTCRA versus 21 per cent in PTCA; $p=0.87$) or target vessel failure (20 per cent in PTCRA versus 24 per cent in PTCA; $p=0.61$). Subgroup analysis focusing on those with diffuse in-stent restenosis did not uncover any differences on follow-up between the groups ($p=0.89$ for target vessel revascularisation and $p=0.82$ for target vessel failure).

The BARASTER registry (Goldberg *et al.* 1997) is a cumulative database of patients treated with PTCRA for in-stent restenosis. Goldberg *et al.* (1998) compared the experience of a consecutive series of patients in the BARASTER registry undergoing PTCRA-PTCA for in-stent restenosis with those found in another registry of patients undergoing PTCA alone for the same condition (NHMRC level III-3). The lesions of those undergoing PTCRA-PTCA were more likely to be longer and located in smaller vessels than those undergoing PTCA alone. Success rates between the groups were similar (98 per cent for PTCRA-PTCA versus 93 per cent for PTCA alone; $p=0.068$), but mean final diameter stenoses favoured those undergoing PTCRA-PTCA [18 per cent (18 per cent) compared to 25 per cent (18 per cent); $p=0.004$].

A comparison between PTCRA and excimer laser coronary angioplasty, both with adjunctive PTCA, in the treatment of in-stent restenosis was performed by Mehran *et al.* (2000). The authors found no significant differences in the pre-intervention characteristics, final post-intervention angiographic analysis or long-term clinical outcomes between the groups.

The results of three case series (Sharma *et al.* 1998, Radke *et al.* 1999, vom Dahl *et al.* 1999) are not discussed.

Effectiveness in lesions refractory to coronary angioplasty

Technical failures may arise during balloon angioplasty due to a failure to cross the lesion with the balloon catheter or to inflate the balloon due to rigidity of the lesion. In some lesions, PTCA may be avoided altogether because of unfavourable findings on coronary angiography. It has been suggested that PTCRA be considered in the management of lesions refractory to PTCA, or for those patients where the only feasible alternative is CABG. However, such patients may not cope well with the rigors of open-chest surgery, particularly those with underlying comorbidities that would be contraindicated for such a procedure, and it is these patients who may be best-served with PTCRA. By partial ablation of the lesion, PTCRA may result in a substantial decrease in plaque burden so that other techniques are unnecessary or may alter plaque morphology such that other adjunctive techniques may be used. Four case series (Rosenblum *et al.* 1992, Brogan *et al.* 1993, Reisman *et al.* 1993b, Sievert *et al.* 1993) enrolling a total of 180 patients have been published that provide some evidence for the effectiveness of PTCRA in these situations (Table 25).

Table 25 Reasons for application of PTCRA following failure of PTCA in four case series.*

Study	Patient inclusion and number of lesions
Brogan *et al.* 1993	Inability to fully dilate the lesion (n=28); inability to cross the lesion with balloon dilatation catheter despite guide wire positioning (n=8); immediate elastic recoil despite adequate balloon expansion (n=7); unknown mechanism (n=7).
Reisman *et al.* 1993b†	Inability to dilate lesion despite PTCA inflation pressure of at least 12 atm (n=67).
Sievert *et al.* 1993	High-degree coronary stenosis or coronary occlusion that could be passed with a guide wire but not with a balloon catheter or recanalisation catheter (n=32).
Rosenblum *et al.* 1992	Failure of PTCA (n=41).‡

* Abbreviations: atm=atmosphere; PTCA=percutaneous transluminal coronary angioplasty; PTCRA=percutaneous transluminal coronary rotational atherectomy.

† Available in abstract form only.

‡ No specific criteria given.

Rosenblum *et al.* (1992) reported on the experience of 36 patients with 41 lesions who had previously failed PTCA. Rotational atherectomy was successful in 40 of 41 lesions (97.6 per cent). In 10 patients (27.8 per cent), PTCRA was used as a single procedure without adjunctive PTCA, while in 26 patients (72.2 per cent) the lesion required adjunctive PTCA. Mean lumen diameter narrowing prior to intervention was 79 per cent (14) decreasing to 35 per cent (16) following PTCRA, and 18 per cent (11) following PTCRA-PTCA. After a mean follow-up of nine months, seven of 24 patients (29.2 per cent) developed clinical or angiographic evidence of restenosis.

Forty one patients with 50 lesions were studied by Brogan *et al.* (1993). After PTCRA, mean per cent diameter stenosis was reduced from 72 per cent (14) to 41 per cent (16). In 44 lesions, the use of adjunctive PTCA resulted in a final diameter stenosis of 25 per cent (17). Procedural success was attained in 37 to 41 (90.2 per cent) patients and six of 17 (35.3 per cent) patients had restenosis after about seven months of follow-up.

In the 67 patients studied by Reisman *et al.* (1993b), 13 underwent PTCRA alone and 54 underwent PTCRA with adjunctive PTCA. The authors report an overall success rate of 96 per cent with a 36 per cent restenosis rate at six months in those patients undergoing PTCRA-PTCA.

Sievert *et al.* (1993) reported that in 15 of 32 (46.9 per cent) cases PTCRA attained a sufficient increase in lumen diameter with the remainder requiring balloon dilatation using adjunctive PTCA. The mean percentage diameter stenosis was reduced from 95 per cent (10) to 33 per cent (6).

The San Antonio Rotablator Study (Kiss *et al.* 1999) observed 111 patients with heavily-calcified lesions of at least 15mm in length undergoing PTCRA with adjunctive PTCA. This case series (NHMRC level IV) reported that the procedure was successfully performed in 98.1 per cent of subjects with a mean luminal gain post-procedure of 1.01 (0.50) mm. Following six months of follow-up, 18 of 64 patients developed restenosis of the previously-treated vessel.

No study was identified that directly compared PTCRA with CABG surgery.

Summary

When conventional PTCA, with or without stent placement, is feasible (in 95 per cent of cases), PTCRA appears to confer no additional benefit to the patient.

In cases of in-stent restenosis, there is limited and conflicting published evidence, and no long-term data, to support the routine use of rotational atherectomy. Expert clinical opinion indicates that, in certain circumstances, rotational atherectomy is a useful adjunctive procedure to increase the success of subsequent angioplasty in achieving satisfactory revascularisation in complicated or calcified lesions.

In specific cases where conventional angioplasty and stenting cannot successfully be undertaken or is associated with a poor clinical or angiographic outcome, PTCRA appears to be an effective adjunctive procedure to increase the likelihood of successful revascularisation. This conclusion is supported by evidence from case series and clinical experience; however, it may not be possible to undertake randomised trials to verify this.

What are the economic considerations?

This section presents a cost analysis of adjunctive rotational atherectomy for lesions of the coronary arteries in Australia using modelled PTCA rates.

The overall cost effectiveness of PTCRA will depend on the cost per course of treatment and the effectiveness of treatment in each indication treated. In addition, the overall cost to the health system will depend on the estimated number of procedures in a given period of time. The previous section has shown the effectiveness of PTCRA varies across indications and the evidence for support is variable. Given that the indications do not have homogeneous outcomes, it was not possible to calculate a single cost effectiveness ratio.

No published cost-effectiveness or cost studies of PTCRA in Australia were identified. However, Australian cost data have been identified from a tertiary setting where PTCRA is provided in Australia (Monash Medical Centre, Melbourne). These data reflect real costs of providing PTCRA as an adjunct to PTCA in a tertiary setting, and analyses in this review have incorporated these cost data.

The section represents only an indication of the potential costs and savings to the health system, rather than an estimate of the cost effectiveness of the technology, by utilising PTCRA as an adjunct to PTCA, when PTCA fails or instead of CABG surgery.

Estimated utilisation

The proportion of PTCRA procedures in relation to artherectomies is variable (Table 4). In extrapolating future utilisation rates, three broad approaches are employed. All techniques use either statistical models or extrapolation derived from existing data. The first approach estimates the number of PTCA procedures to be undertaken between 2001 and 2005. The second uses the current figure of two per cent as the percentage of all PTCA procedures receiving adjunctive PTCRA. The last approach uses local cost data to estimate potential costs, or savings, to the Australian health system.

The relationship between the number of PTCA procedures and latent temporal characteristics is assumed to take on one of several forms (Table 26 and Figure 10). Overall, the estimated number of PTCA procedures is sensitive to the particular relationship assumed with almost a two-fold difference existing among the range of estimates. The estimates derived from the log-normal model are extreme. However, the distinction between estimates derived from the linear, quadratic or cubic models are not as clearly defined. This analysis proceeded with the assumption that the linear model provides a reasonable approximation of the potential number of PTCA procedures in the next half-decade.

Table 26 Estimated number and 95% confidence intervals of PTCA procedures (´ 1,000) for 2001-2005 allowing for particular assumptions in the temporal relationship.*

Year	Linear	Quadratic	Log-normal
2001	21.1 (18.5, 23.6)	26.6 (25.6, 27.5)	31.1 (30.6, 31.5)
2002	22.6 (19.9, 25.2)	29.7 (28.6, 30.9)	36.8 (36.1, 37.4)
2003	24.0 (21.3, 26.8)	33.1 (31.8, 34.5)	43.5 (42.7, 44.3)
2004	25.5 (22.6, 28.5)	36.7 (35.1, 38.4)	51.5 (50.4, 52.5)
2005	27.0 (24.0, 30.1)	40.5 (38.6, 42.5)	60.9 (59.5, 62.3)
Adjusted R^2	0.9594	0.9983	0.9923†

* Abbreviations: PTCA=percutaneous transluminal coronary angioplasty; R^2=coefficient of determination.
† Pseudo-R^2.

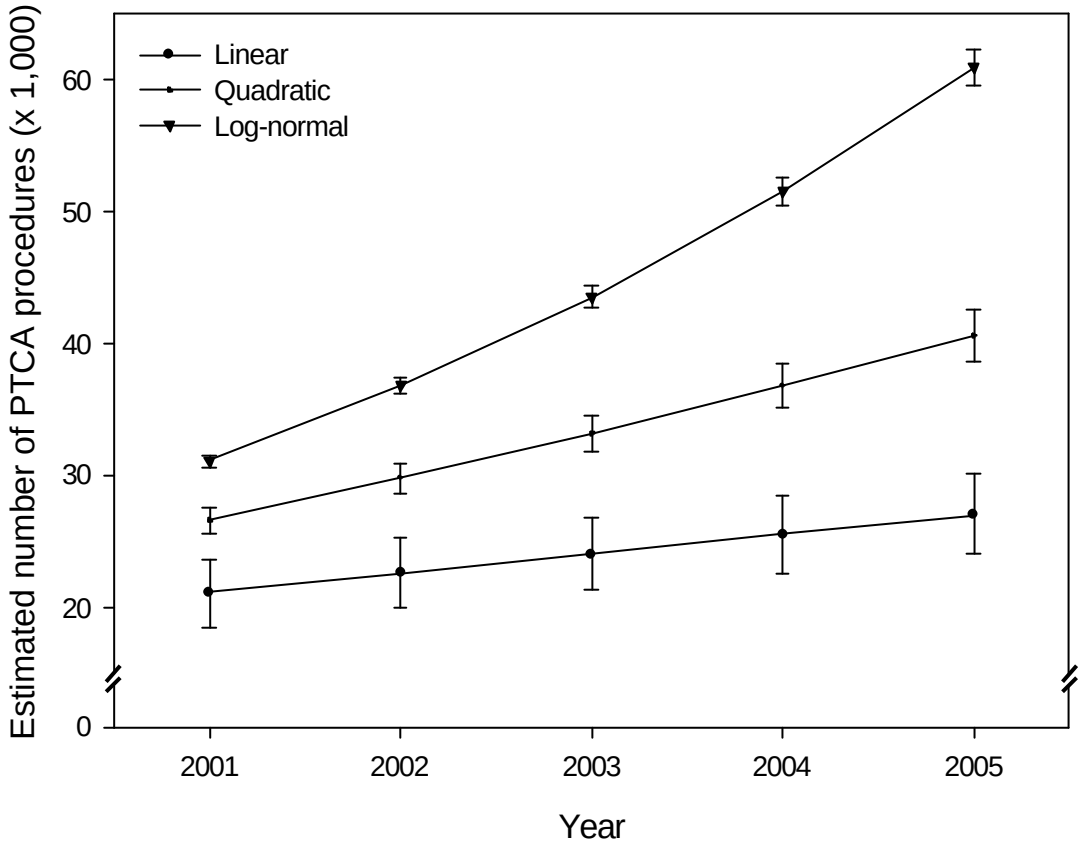

Figure 10 Estimated number of PTCA procedures for 2001-2005.

The proportion of PTCRA procedures, in comparison to the number of PTCA procedures, is variable (Table 4). In 1993, 1.4 per cent of all PTCA procedures involved PTCRA. In 1998, this figure was 2.0 per cent. Expert clinical opinion suggests that although the number of PTCRA procedures is likely to increase due to continued increase in the number of PTCA procedures undertaken, PTCRA is expected to be used in two per cent of cases in the long-term.

Cost of PTCRA

The total cost of a PTCRA procedure per year includes both capital costs and costs associated with operating the device. Expert clinical opinion and local data suggest that an average of 70 minutes per procedure is required. A summary of the incremental costs associated with providing PTCRA as an adjunct to PTCA, for both local and national provision of PTCRA, is presented in Table 27.

The capital cost per annum, while assumed to be borne by the health provider, is calculated as the constant payment required per year with the expected cost of capital, effective life and present value of the capital equipment. In a single tertiary setting, the capital cost per annum is $5,380. If five PTCRA procedures are conducted per annum, the cost per PTCRA procedure is $1,076 (see Table 27, Monash Medical Centre 2001 data). If extrapolated to a national level, capital cost per annum remains at $5,380 but procedural cost is reduced to $517 (i.e. $5,380/10.4). Readers should note that this assumes that 25 PTCRA units (estimate provided by Boston Scientific Pty Ltd) are used to perform all 260 PTCRA procedures (see Davies & Senes 2000) per annum at an average of 10.4 procedures per PTCRA unit.

Table 27 Local (i.e. Australian) incremental costs of performing PTCRA as an adjunct to PTCA*

Item	Monash Medical Centre 2001†	Estimate of Australian 1999 costs†	Comments
Major capital equipment			
Cost of PTCRA console, $	22,000	22,000	Cost of unit to Monash Medical Centre
Estimated life of console, years	5	5	
Cost of equipment per year for estimated life, $	4,400	4,400	
Annual maintenance cost, $	100	100	Purchase of console comes with a 1-year guarantee.
Opportunity cost, %	4	4	
Total equipment cost per year, $	5,380	5,380	
Estimated number of units in Australia, n		25	Estimate provided by Boston Scientific Pty Ltd
Number of PTCRA procedures, n	5	260	No. of PTCRA procedures in 1999
Estimated number of procedures per unit, n	5	10.4	
Capital cost per procedure, $	**1,076**	**517**	
Equipment cost per procedure			
PTCRA advancers, $	1,080	1,080	
PTCRA catheters, $	2,050	2,050	Unit price is $1,025. A minimum of 2 burrs/catheters used per procedure.
PTCRA guide wires, $	300	300	Unit price is $1,500 for a box of 5 wires ($300 per wire).
Nitrogen gas cylinders, $	25	25	Unit price is $50 for N_2 gas cylinder that lasts 2 PTCRA procedures.
Consumables	524	524	Drapes, angioplasty kit $200; gowns, drugs, films $80; introducer sheath $14; guiding catheter $180; arterial contrast $50,
Total equipment cost per procedure, $	3,979	3,979	
Staffing costs per procedure			
Average length of procedure, min	70	70	30min prior to PTCRA, 20min to introduce wires, 20min for PTCRA procedure: all additional to PTCA
Total hourly wage rate for catheter laboratory staff, $‡	246	246	
Total staffing cost per procedure, $	287	287	
Total treatment cost per procedure, $	**4,266**	**4,266**	**Equipment cost plus staffing cost**

* Abbreviations: PTCRA=percutaneous transluminal coronary rotational atherectomy.

† All estimates are rounded up to the nearest unit.

‡ Hourly rates from a teaching hospital: cardiologist, $96.10; registrar, $30.68; radiographer, $29.24; scrub nurse, $26.03; 1.5 circulating nurses, $23.76. cardiac technologist:, $27.74.

The total treatment cost of $4,266 relates to the single-use devices and consumables utilised in the procedure, and staff time. However, this also assumes a maximum of two burrs per procedure are used (additional burrs used per procedure will clearly increase procedural costs). While 1999 data demonstrate that two per cent of all coronary interventional procedures require PTCRA, expert clinical opinion suggests fewer procedures may be conducted if referrals from physicians/fellow cardiologists to the 'trained cardiologist' providing PTCRA are not considered. As a result, such patients are often re-admitted for further interventional procedures or surgery within the subsequent 24 hour period. This may be reflected in the reported reduction of PTCRA procedures by 59 per cent from 1997 to 1998 and by 10 per cent from 1998 to 1999.

Cost of PTCA and CABG

The hospitalisation costs (DHAC 2001) of PTCA and CABG are presented in Table 28. The major assumption underlying the use of these estimates was the similarity in the base population providing the primary data. For most indications evaluated in this report, the natural history of a series of patients receiving PTCA or CABG who would have benefited from the use of PTCRA is not available. Only a well-conducted prospective cohort study or randomised controlled trial will be able to provide these estimates.

Table 28 Average lengths of stay and costs associated with PTCA and CABG in public and private sector hospitals (DHAC 2001).*

DRG Code	Description	Average Length of Stay (Days)		Average Cost per DRG ($)	
		Public	Private	Public	Private
F05A	Coronary bypass with invasive investigational procedure with catastrophic complications	16.32	16.53	23,431	15,883
F05B	Coronary bypass with invasive investigational procedure without catastrophic complications	12.36	12.08	18,496	12,905
F06A	Coronary bypass without invasive investigational procedure with catastrophic or serious complications	9.57	11.48	16,219	12,763
F06B	Coronary bypass without invasive investigational procedure without catastrophic or serious complications	7.30	8.55	12,818	10,523
F15Z	Percutaneous coronary angioplasty without AMI with stent	2.62	3.66	5,186	6,399
F16Z	Percutaneous coronary angioplasty without AMI without stent	2.81	3.48	4,260	5,268

* Abbreviations: CABG=coronary artery bypass graft; PTCA=percutaneous transluminal coronary angioplasty.

Indicative cost-analysis of adjunctive PTCRA

The local cost of PTCA in a public setting (see Table 28; F15Z) with adjunctive PTCRA is $9,452 per procedure (i.e. 'percutaneous coronary angioplasty without AMI with stent' @ $5,186 + PTCRA @ $4,266). If two per cent of all coronary interventional procedures are considered appropriate for PTCRA, a simple cost analysis using modelled PTCA utilisation rates suggests that between 370 and 472 PTCRA procedures will be conducted in 2001 at an additional cost to the health system of between $1,578,420 and $2,013,552 (Table 29). Estimated procedural costs for years 2002 to 2005 are also presented in Table 29. However, this assumes there are no adverse events requiring re-admission or emergency surgery. The reader is advised to consider the data carefully since current PTCRA usage is much lower than the modelled data appear to predict. If this remains the case, future PTCRA costs are likely to be reduced further.

Table 29 Estimated number and costs of adjunctive PTCRA procedures in public hospitals for 2001-2005*

Year	PTCRA, n	PTCRA incremental cost, $ million
2001	370 - 472	1.58 – 2.01
2002	398 - 504	1.70– 2.15
2003	426 - 536	1.82 – 2.29
2004	452 - 570	1.93 – 2.43
2005	480 - 602	2.05 – 2.57

* Abbreviations: PTCA=percutaneous transluminal coronary rotational atherectomy;

Indicative cost-analysis of PTCRA in lesions refractory to PTCA or when CABG is contraindicated

Reasons for failure of PTCA in four case series (Rosenblum *et al.* 1992, Brogan *et al.* 1993, Reisman *et al.* 1993b, Sievert *et al.* 1993) are listed in Table 25. For patients such as these, the only feasible alternative is CABG. At the present time, there is no published study comparing PTCRA to CABG in a single population of patients, probably due to the ethical difficulty and infeasibility of such an endeavour. In addition, there is no report or estimate of the number or percentage of patients undergoing CABG surgery for which PTCRA would prove beneficial. Since 574, or 3.85 per cent, of all CABG procedures in Australia in 1998 were for single-vessel bypass without a concomitant procedure (see page 12 and Davies & Senes 2001), an assumption has been made that PTCA with adjunctive PTCRA can, at best, be performed on all these patients, thereby potentially avoiding the need for CABG procedures in these patients.

However, this assumption is problematic because while not all CABG procedures can be converted to PTCRA (i.e. contraindicated for angioplasty because of anatomical placement of blockages, e.g. left main disease), the proportion of single-vessel CABG procedures able to be converted to PTCRA is not known. As a result, costs presented below are indicative only and are not relevant outside an Australian context.

An indicative cost analysis comparing the two procedures, and in which the best-case scenario is represented, is summarised in Table 30. It is assumed that PTCRA is adjunctive to PTCA and that the two procedures do not significantly alter the course of treatment of patients compared to PTCA or CABG (an assumption that may not hold if patients have poorer pre-procedural characteristics, an increased risk for adverse events, poor outcomes, etc.). Furthermore, patients with refractory lesions are also more likely to possess significant complex comorbidities.

When compared with CABG surgery (Table 30), PTCRA adjunctive to PTCA could represent an additional saving of $3,366 per CABG procedure avoided (i.e. 'coronary bypass without invasive investigational procedure without catastrophic or serious complications' @ $12,818 – [PTCA @ $5,186 + PTCRA @ $4,266]), or a maximum saving of $1,932,084 to the health system. However, this assumes that all single-vessel CABG procedures do progress to PTCRA and that all outcomes do not require further percutaneous or surgical intervention. Readers should exercise caution when considering these results because there are no supporting data to support the assumption that all single-vessel CABG procedures can be adequately managed by PTCA with adjunctive PTCRA.

Table 30 Estimated cost CABGs avoided due to adjunctive PTCRA procedures in public hospitals, using 1998 data

Outcome	Number, n	CABG	PTCA + PTCRA	Maximum saving
Cost, $	1	12,818	9,452	3,366
Cost, $	574	7,357,532	5,425,448	1,932,084

Summary

Cost-effectiveness ratios could not be determined. Australian cost data demonstrate that PTCRA, used as an adjunct to PTCA in the two per cent of cases where PTCRA is deemed, would be expected to cost the health system less than an additional $2 million per year. In addition, PTCRA is estimated to save the health system, at best, $1.9 million when used in lesions refractory to PTCA or as an alternative to CABG for single-vessel disease. However, estimated cost savings may be misleading since this assumption is problematic - the proportion of single-vessel CABG procedures able to be converted to PTCRA is not known. Costs are indicative only and are not relevant outside an Australian context.

Conclusions

The available evidence supporting different clinical uses of rotational atherectomy is incomplete and the quality of evidence is of variable standard. Available high-level evidence does not address some important clinical issues. In some instances, conflicting results are apparent.

Safety

The available evidence from RCTs suggests that PTCRA with or without PTCA is no more likely to result in death, Q-wave infarcts or emergency surgery than PTCA alone either during the in-hospital period or within six months of the procedure. Patients are also less likely to experience angiographic dissection or proceed to bailout stenting. However, as this review went to print, vom Dahle *et al.* (2002) published six month data from their ARTIST RCT (in which in-stent restenosis was assessed following PTCRA and PTCA) reporting that six month event-free survival was significantly higher after PTCA (91.3 per cent) compared with PTCRA (79.6 per cent. p=0.0052).

Since perforation rates - the major and most immediately recognisable adverse event associated with interventional cardiology procedures - are not statistically significantly different from those associated with PTCA, it would appear the PTCRA is as safe as PTCA in the first 24 hours of the procedure. However, there is insufficient data to conclude whether PTCRA is as safe as PTCA in revascularising different types of coronary artery lesions. Minor complications such as temporary vessel spasm and slow/no flow phenomena are also increased.

Effectiveness

When conventional PTCA, with or without stent placement, is feasible (in 95 per cent of cases), PTCRA appears to confer no additional benefit to the patient. This conclusion is supported by evidence from randomised trials.

In cases of in-stent restenosis, there is limited and conflicting published evidence, and no long-term data, to support the routine use of rotational atherectomy. Expert clinical opinion indicates that, in certain circumstances, rotational atherectomy is a useful adjunctive procedure to increase the success of subsequent angioplasty in achieving satisfactory revascularisation in complicated or calcified lesions.

PTCRA appears to be an effective adjunctive procedure for increasing the likelihood of successful revascularisation in specific cases where conventional angioplasty and stenting cannot be undertaken. It also may be applicable when these procedures are associated with a poor clinical or angiographic outcome, including some cases where CABG surgery may be the preferred therapeutic modality.. This conclusion is supported by evidence from case series and clinical experience; however, it may not be possible to undertake randomised trials to verify this.

Cost-effectiveness

Cost-effectiveness ratios could not be determined given the limitations of the data on effectiveness and the paucity of robust cost estimates arising from high-quality studies.

Australian cost data demonstrate that PTCRA, used as an adjunct to PTCA in the two per cent of cases where PTCRA is deemed appropriate, would be expected to cost the health system less than an additional $2 million per year. In addition, PTCRA is estimated to save the health system, at best, $1.9 million when used in lesions refractory to PTCA or as an alternative to CABG for single-vessel disease. However, these cost savings may be misleading since the assumption made is problematic - the proportion of single-vessel CABG procedures able to be converted to PTCRA is not known. Costs are indicative only and are not relevant outside an Australian context.

Recommendations

MSAC recommended that on the evidence pertaining to percutaneous transluminal coronary rotational atherectomy (PTCRA):

1) Public funding is supported for the following specific indications:

    a) For revascularisation of complex and heavily calcified coronary artery lesions which cannot be treated by percutaneous transluminal coronary angioplasty (PTCA) alone or when previous PTCA attempts have not been successful; and

    b) For revascularisation of complex and heavily calcified coronary artery stenoses where coronary artery bypass graft (CABG) surgery is contra-indicated.

2) Public funding is not supported for the following indications:

    a) For revascularisation of coronary artery stenoses which can be satisfactorily treated by PTCA alone, with or without stent placement; and

    b) For revascularisation of coronary artery in-stent restenoses as a result of prior coronary artery intravascular interventions (since no long-term data exist and short-term data are conflicting).

The Minister for Health and Ageing accepted this recommendation on 17 September 2002.

Appendix A MSAC terms of reference and membership

MSAC's terms of reference are to:

- advise the Minister for Health and Ageing on the strength of evidence pertaining to new and emerging medical technologies and procedures in relation to their safety, effectiveness and cost-effectiveness and under what circumstances public funding should be supported;
- advise the Minister for Health and Ageing on which new medical technologies and procedures should be funded on an interim basis to allow data to be assembled to determine their safety, effectiveness and cost-effectiveness;
- advise the Minister for Health and Ageing on references related either to new and/or existing medical technologies and procedures; and
- undertake health technology assessment work referred by the Australian Health Ministers' Advisory Council (AHMAC), and report its findings to AHMAC.

The membership of MSAC has a mix of clinical expertise covering pathology, nuclear medicine, surgery, specialist medicine and general practice, plus clinical epidemiology and clinical trials, health economics, consumers, and health administration and planning:

Member	Expertise or Affiliation
Dr Stephen Blamey (Chair)	general surgery
Professor Bruce Barraclough	general surgery
Professor Syd Bell	pathology
Dr Paul Craft	clinical epidemiology and oncology
Professor Ian Fraser	reproductive medicine
Associate Professor Jane Hall	health economics
Dr Terri Jackson	health economics
Ms Rebecca James	consumer health issues
Professor Brendon Kearney	health administration and planning
Mr Alan Keith	Assistant Secretary, Diagnostics and Technology Branch, Commonwealth Department of Health and Aging
Associate Professor Richard King	internal medicine
Dr Ray Kirk	health research
Dr Michael Kitchener	nuclear medicine
Mr Lou McCallum	consumer health issues
Emeritus Professor Peter Phelan	paediatrics
Dr Ewa Piejko	general practice
Dr David Robinson	plastic surgery
Professor John Simes	clinical epidemiology and clinical trials
Professor Richard Smallwood	Chief Medical Officer, Commonwealth Dept Health & Aging
Professor Bryant Stokes	neurological surgery, representing the Australian Health Ministers' Advisory Council
Associate Professor Ken Thomson	radiology
Dr Douglas Travis	urology

Appendix B Supporting committee

Supporting committee for MSAC application 1036 - Rotational Atherectomy for Complex Lesions of the Coronary Arteries

Dr David Robinson (Chair – from October 2001) MBBS, FRCS, FRACS, President of Senior Medical Staff Association Princess Alexandra Hospital, Brisbane	member of MSAC
Dr Ross Blair (Chair – until October 2001) MBChB, RACS Thoracic and Vascular Surgeon Director of Vascular Surgery Waikato Hospital, New Zealand	member of MSAC (until October 2001)
Dr David Jarvis MB ChB FRACGP BA BLitt Canberra, ACT	Nominated by the Royal Australian College of General Practitioner
Associate Professor Richmond Jeremy MBBS FRACP PhD(Medicine) Department of Cardiology Royal Price Alfred Hospital Sydney, New South Wales	Nominated by the Royal Australian College of Physicians
Mr Ivan Kayne Donvale, Victoria	Nominated by the Consumers' Health Forum of Australia
Associate Professor Ian Meredith MBBS(Hons) BSc(Hons) PhD FRACP FACC Director Cardiac Catheterisation and Interventional Laboratories Head Cardiovascular Research Group Monash Medical Centre, Victoria	Co-opted member
Dr Mark Pitney MBBS FRACP MSCAI Director Cardiac Catheterisation Laboratories Eastern Heart Clinic Prince of Wales Hospital Sydney, New South Wales	Nominated by the Royal Australian College of Physicians
Professor Julian Smith MBBS MS FRACS FACS Department of Surgery Monash Medical Centre, Victoria	Co-opted member

Appendix C Randomised controlled trials included in the review

Study	Location	Dates of Enrolment	Characteristics of the Study Population†			Length of Follow-up
			Size	Age (years) Mean (SD)	Sex Ratio (M:F)	
Safian *et al.* 2001	USA	?‡	222	I=67 (10) C=65 (10)	I=72:32 C=83:35	6 months
Whitlow *et al.* 2001	USA	?	497	I=62.3 (10.6) C=62.4 (11.2)	I=157:92 C=175:73	1 year
Buchbinder *et al.* 2000#	USA	?	675	I=63.6 C=64.4	I=223:105 C=239:103	In-hospital
Dill *et al.* 2000	Germany	May 1992 to May 1996	502	I=61 (9) C=62 (9)	I=185:67 C=186:64	6 months
Sharma *et al.* 1999#	USA	?	100	?	?	In-hospital
Eltchaninoff *et al.* 1997	France	?	50	I=61 (11) C=56 (11)	I=21:5 C=22:2	In-hospital
Niazi *et al.* 1997#	Saudi Arabia	To Feb 1997	150	?	I=130:20 C=132:18	6 months
Reifart *et al.* 1997§	Germany	Oct 1991 to Aug 1992 Jan 1993 to Dec 1993	685	I=61.6 (10.0) C(a)=62.5 (9.5) C(b)=61.7 (8.8)	I=184:47 C(a)=180:42 C(b)=180:52	6 months to 1 year
Reisman *et al.* 1997#	USA	?	442	?	I=135:87 C=154:66	?
Guerin *et al.* 1996	France	Apr 1992 to Sep 1993	64	I=64.6 (10.8) C=63.3 (10.4)	I=25:7 C=23:9	6 months
Danchin *et al.* 1995¶	France	Jan 1991 to Dec 1992	100	I=57 (10) C=58 (10)	I=42:8 C=43:7	In-hospital

* Abbreviations: C=comparison group; F=female; I=intervention group; M=male; SD=standard deviation.
† Information is given for intervention and comparison groups.
‡ Unstated, unclear, or unknown.
§ C(a)=percutaneous transluminal coronary angioplasty, C(b)=excimer laser coronary angioplasty.
# Available in abstract form only.
¶ Randomised crossover trial. Primary results prior to crossing of therapies analysed.

Appendix D Health technology agencies websites searched

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Agency for Healthcare Research and Quality. http://www.ahrq.gov/ (Accessed 1 March 2001).

Alberta Heritage Foundation for Medical Research (AHFMR). http://www.ahfmr.ab.ca/index.html (Accessed 1 March 2001).

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Institute for Clinical Systems Improvement. http://www.icsi.org/talist.htm (Accessed 1 March 2001).

Institute of Technology Assessment of the Austrian Academy of Science. http://www.oeaw.ac.at/ita/welcome.htm (Accessed 1 March 2001).

International Network of Agencies for Health Technology Assessment (INHATA). http://www.inahta.org/ (Accessed 1 March 2001).

International Society of Technology Assessment in Health Care (ISTAHC). http://www.istahc.org/ (Accessed 1 March 2001).

Medical Technology & Practice Patterns Institute (MTPPI). http://www.mtppi.org/ (Accessed 1 March 2001).

Medical Technology Assessment Group (M-TAG). http://www.m-tag.net/ (Accessed 1 March 2001).

Minnesota Health Technology Advisory Council. http://www.health.state.mn.us/htac/ (Accessed 1 March 2001).

The National Coordinating Centre for Health Technology Assessment (NCCHTA). http://www.hta.nhsweb.nhs.uk/ (Accessed 1 March 2001).

NHS Centre for reviews and dissemination, University of York. http://nhscrd.york.ac.uk/welcome.html (Accessed 1 March 2001).

National Horizon Scanning Centre. http://www.bham.ac.uk/PublicHealth/horizon/ (Accessed 1 March 2001).

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Abbreviations

atm	atmosphere
BSPL	Boston Scientific Pty Ltd
CABG	coronary artery bypass graft
CER	cost-effectiveness ratio
CI	confidence interval
DCA	directional coronary atherectomy
df	degrees of freedom
F	French
ITT	intention to treat
IU	International Unit
IVUS	intravascular ultrasonography
LAD	left anterior descending artery
LCx	left circumflex artery
MACE	major adverse cardiac events
MBS	Medicare Benefits Scheme
MI	myocardial infarction
MLD	minimal lumen diameter
NACI	New Approaches to Coronary Intervention (registry)
NHLBI	National Heart, Lung, and Blood Institute (United States)
NHMRC	National Health and Medical Research Council
OR	odds ratio
PTCA	percutaneous transluminal coronary angioplasty
PTCRA	percutaneous transluminal coronary rotational atherectomy/ablation
Q	Cochran Q statistic for heterogeneity
QUOROM	Quality of Reporting of Meta-analyses
R^2	coefficient of determination
RA	rotational atherectomy/ablation
RCA	right coronary artery
RCT	randomised controlled trial
RD	risk difference
rpm	revolutions per minute
RR	relative risk/risk ratio
SD	standard deviation
TEC	transluminal extraction catheter
TIMI	Thrombolysis in Myocardial Infarction (study)

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